Battelle
The Business of Innovation

Environmental Technology Verification Program

Advanced Monitoring Systems Center

Test/QA Plan for Verification of Personal Cascade Impactor Samplers (PCISs) for Measuring Ambient Particulate Matter (PM)

TEST/QA PLAN

for

Verification of
Personal Cascade Impactor Samplers (PCISs)
for
Measuring Ambient Particulate Matter (PM)

January 11, 2006

Prepared by

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ETV Advanced Monitoring Systems Center

Test/QA Plan for Verification of Personal Cascade Impactor Samplers (PCISs) for Measuring Ambient Particulate Matter (PM)

Version 1

January 11, 2006

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LIST OF ACRONYMS

AMS – Advanced Monitoring Systems Center
A/C – Alternating current
BCO – Battelle Columbus Ohio Operations
CoC – Chain-of-custody
EPA – Environmental Protection Agency
ETV – Environmental Technology Verification
FRM – Federal Reference Method
ISL – Instrument Services Laboratory
LRB – Laboratory record book
NIST – National Institute of Standards and Technology
PCIS – Personal Cascade Impactor Sampler
PE – Performance evaluation
PES – Performance evaluation standard
PEM – Personal Environmental Monitor
PM – Particulate matter
PM2.5 – Particulate matter with particle diameter of less than or equal to 2.5 µm
PTFE – Polytetrafluoroethylene (Teflon®)
QA – Quality Assurance
QC – Quality Control
QS – Quality assurance standard
QMP – Quality Management Plan
RPD – Relative percent difference
SOP – Standard operating procedure
SRM – Standard reference material
TSA – Technical systems audit
XRF – X-ray fluorescence

SECTION A

PROJECT MANAGEMENT

A4 VERIFICATION TEST ORGANIZATION

The verification test will be conducted under the auspices of the U.S. Environmental Protection Agency (EPA) through the Environmental Technology Verification (ETV) Program. It will be performed by Battelle, which manages the ETV Advanced Monitoring Systems (AMS) Center through a cooperative agreement with EPA. The scope of the AMS Center covers verification of monitoring technologies for contaminants and natural species in air, water, and soil.

This verification test will be conducted by Battelle personnel, with telephone assistance or equipment repair/maintenance as needed by the vendor who will be having the performance of their personal cascade impactor sampler (PCIS) verified. The laboratory and environmental chamber testing will occur at Battelle headquarters (BCO), located in Columbus, OH. In situ field tests involving human subjects wearing the PCISs for a period of 48 hours will also be conducted, and the PCISs will be returned to the BCO laboratories for analysis. XRF analyses will be carried out by Chester LabNet according to EPA Compendium Method IO-3.3[1]. Quality assurance (QA) oversight will be provided by the Battelle Quality Manager, and also by the EPA AMS Center Quality Manager at her discretion. The organization chart in Figure 1 identifies the responsibilities of the organizations and individuals associated with the verification test. Roles and responsibilities are defined further below.

A4.1 Battelle

Marielle C. Brinkman is the AMS Center Verification Test Coordinator for this test. In this role, she will have overall responsibility for ensuring that the technical, schedule, and cost goals established for the verification test are met. Specifically, she will:

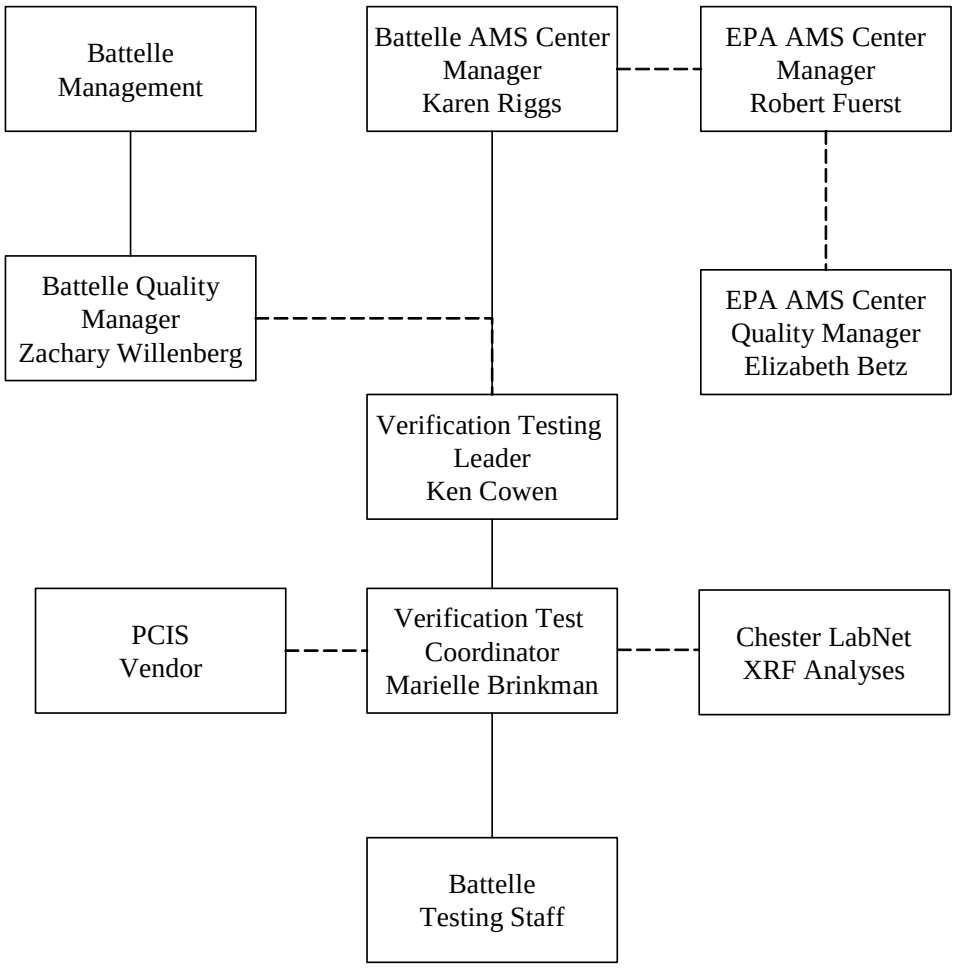

Figure 1. Organization Chart

- Assemble a team of qualified technical staff to conduct the verification test.
- Direct the team (Battelle and Chester LabNet) in performing the verification test in accordance with this test/QA plan.
- Ensure that all quality procedures specified in this test/QA plan and in the AMS Center Quality Management Plan[2] (QMP) are followed.
- Prepare the draft and final test/QA plan, verification reports, and verification statements.

- Revise the draft test/QA plan, verification reports, and verification statements in response to reviewers' comments.
- Respond to any issues raised in assessment reports and audits, including instituting corrective action as necessary.
- Serve as the primary point of contact for vendor representatives.
- Coordinate distribution of the final test/QA plan, verification reports, and statements.
- Establish a budget for the verification test and manage staff to ensure the budget is not exceeded.
- Ensure that confidentiality of sensitive vendor information is maintained.

Dr. Kenneth Cowen will serve as the Verification Testing Leader for this verification test. As such, Dr. Cowen will provide technical guidance and oversee the various stages of verification testing. He will:

- Dr. Cowen will provide technical input on particle sampling procedures for the test/QA Plan and the verification testing procedures.
- In his role as technical leader, Dr. Cowen will be assisted by Vladimir Kogan, who will provide technical expertise in the areas of aerosol generation, sampling, and characterization.
- Support Ms. Brinkman in preparing the test/QA plan and organizing the testing.
- Review the draft and final test/QA plan.
- Review the draft and final verification reports and statements.

Ms. Karen Riggs is Battelle's manager for the AMS Center. Ms. Riggs will

- Review the draft and final test/QA plan.
- Review the draft and final verification reports and verification statements.
- Ensure that necessary Battelle resources, including staff and facilities, are committed to the verification test.

- Ensure that confidentiality of sensitive vendor information is maintained.
- Support Ms. Brinkman in responding to any issues raised in assessment reports and audits.
- Maintain communication with EPA's technical and quality managers.
- Issue a stop work order if Battelle or EPA QA staff discovers adverse findings that will compromise test results.

Battelle Technical Staff will conduct and oversee the testing of the PCISs during the verification test. Battelle staff will be working in the BCO environmental chamber and air quality laboratories and will be in communication with the PCIS vendor as needed. The responsibilities of the technical staff will be to:

- Become familiar with the operation and maintenance of the PCIS through instruction by the vendor.
- Assure that verification testing is performed as described in the test/QA plan.
- Communicate with Chester LabNet on the planning, performance, and reporting of the ambient air metals sample analysis.
- Recruit human subjects for the field testing of the PCIS.
- Communicate the field testing protocol and familiarize the subjects with the equipment, as needed.
- Weigh reference sampler and PCIS substrates before and after testing and deliver gravimetric data to the Verification Test Coordinator within ten days of collection.
- Communicate and coordinate with the PCIS vendor on operation and maintenance of the PCIS.
- Record qualitative observations about the maintenance and operation of the PCIS during testing.
- Provide input on test procedures, PCIS operation and maintenance, and chamber conditions for the draft verification reports.

Mr. Zachary Willenberg is Battelle's Quality Manager for the AMS Center. Mr. Willenberg will:

- Review the draft and final test/QA plan.
- Conduct a technical systems audit at least once during the verification test, or designate other QA staff to conduct the audit.
- Audit at least 10% of the verification data.
- Prepare and distribute an assessment report for each audit.
- Verify implementation of any necessary corrective action.
- Request that Battelle's AMS Center Manager issue a stop work order if audits indicate that data quality is being compromised.
- Provide a summary of the QA/QC activities and results for the verification reports.
- Review the draft and final verification reports and verification statements.
- Assume overall responsibility for ensuring that the test/QA plan is followed.

A4.2 PCIS Vendor

The responsibilities of the PCIS vendor is as follows:

- Review and provide comments on the draft test/QA plan.
- Accept (by signature of a company representative) the test/QA plan prior to test initiation (see page 4).
- Provide four PCIS(s), complete with Leland Legacy sampling pumps, for evaluation during the verification test.
- Provide all other equipment/supplies/reagents/consumables needed to operate their PCIS for the duration of the verification test.
- Make available, as needed, a representative to maintain or repair their technology throughout the duration of the verification test.
- Provide written instructions for routine operation of their PCIS, including a daily checklist of diagnostic and/or maintenance activities.

- Review and provide comments on the draft verification report and statement for the PCIS.

A4.3 EPA

EPA's responsibilities in the AMS Center are based on the requirements stated in the "Environmental Technology Verification Program Quality Management Plan" (EPA QMP).[3] The roles of specific EPA staff are as follows:

Ms. Elizabeth Betz is EPA's AMS Center Quality Manager. For the verification test, Ms. Betz will:

- Review the draft test/QA plan.
- Perform at her option one external technical system audit during the verification test.
- Notify the EPA AMS Center Manager of the need for a stop work order if any external audit indicates that data quality is being compromised.
- Prepare and distribute an assessment report summarizing results of any external audit.
- Review draft verification reports and statements.

Mr. Robert Fuerst is EPA's manager for the AMS Center. Mr. Fuerst will:

- Review the draft test/QA plan.
- Approve the final test/QA plan.
- Review the draft verification report and statements.
- Oversee the EPA review process for the verification report and statements.
- Coordinate the submission of the verification report and statements for final EPA approval.

A4.4 Chester LabNet

The responsibilities of Chester LabNet in this test are as follows:

- Conduct metals analyses on reference and test sampler substrates according to EPA Compendium Method IO-3.3.[1]

- Maintain substrate sample chain-of-custody (CoC).
- Calculate the metals results in terms of concentrations as specified in the EPA method,[1] and provide a data package to Battelle that includes sample and QC sample results, all completed CoC sheets, analysis records, calibration data, and QA information.

A5 BACKGROUND

The ETV Program's AMS Center conducts third-party performance testing of commercially available technologies that detect or monitor natural species or contaminants in air, water, and soil. Stakeholder committees of buyers and users of such technologies recommend technology categories, and technologies within those categories, as priorities for testing. PCISs were identified as a priority technology category through the AMS Center stakeholder process. Epidemiological studies have often used central, fixed-site air monitors to determine exposures, although these monitors do not adequately represent actual human exposures. To better validate risk estimates, lightweight and user-friendly personal samplers that simultaneously separate and collect particles by size, thus allowing the characterization of size-specific chemical constituents in air, are needed. The purpose of this verification is to evaluate the PCIS on the basis of sampling efficiency comparability with more well known reference samplers, ability to collect detectable levels of metals in ambient air, ruggedness, ease of use, reliability and acceptability to volunteer subjects.

A6 VERIFICATION TEST DESCRIPTION AND SCHEDULE

A6.1 Summary of Technology Category

Ambient particulate matter (PM) is an air pollutant that has become a major public health concern in the past 10 years. Health effects studies have typically used ambient monitors to represent human exposures. Understanding of individual exposures to PM can be significantly

improved by the use of personal monitors, which naturally incorporate the effects of such factors as indoor pollutant sources and human time/activity patterns. Newly introduced into the marketplace, PCISs are miniaturized personal cascade impactor samplers that are worn in the individual's breathing zone, commonly clipped to the shirt collar, and allow separation and collection of airborne particles onto a substrate in several size ranges, typically ranging from 0.1 - 10 µm. These samplers are coupled to small, high efficiency, battery-operated pumps capable of sampling for 24 hours on a single battery charge.

Prior to their introduction to the marketplace, the PCISs are characterized in the laboratory to corroborate the manufacturer's stated cutpoints, and evaluate collection efficiency and particle loading. Known particulate standards, such as monodisperse polystyrene latex particles and polydisperse aerosols; e.g., ammonium sulfate and ammonium nitrate, are commonly used for these characterizations. So as to interfere as little as possible with the ensuing chemical analyses, common collection substrate materials include PTFE (Teflon®) and quartz for the analysis of inorganic species, and aluminum for the analysis of organic species.

This verification test will not repeat the manufacturers' characterizations described in the preceeding paragraph, but will instead proceed to the next logical step and evaluate the PCIS on the basis of comparability with the sampling efficiency of more well known reference samplers, ability to measure detectable levels of metals in ambient air, ruggedness, ease of use, reliability, and acceptance among volunteer subjects. Although our evaluations will include the use of human subjects, formal communications with the Battelle Internal Review Board indicate that this study will not require the preparation of a Human Subject's Committee application, because wearing the PCISs will not expose study participants to risk, and time/activity diaries and questionnaire responses will not be directly linked to the study participants' names or other unambiguous identifying information.

In performing the verification test, Battelle will follow the technical and QA procedures specified in this test/QA plan and will comply with the data quality requirements in the AMS Center QMP,[2] and of the ETV QMP.[3]

A6.2 Verification Test Description

The verification test will include four tasks: A) Pump Testing, B) Sampling Efficiency Comparisons, C) Sampling Metals in Ambient Air, and D) PCIS Ease of Use, Reliability and Subject Acceptance. These tasks are described in Sections A6.2.1 - 4.

A6.2.1 Task A: Pump Testing

This task will focus on the evaluation of the duration of operation, and ruggedness, i.e., operation under various temperature/humidity and pressure load conditions, of the Leland Legacy pump in simulated moderate and extreme real-world conditions. Each of the tests conducted in Task A will involve four pumps and will be repeated three times in order to measure inter- and intra-pump variability. Ruggedness testing that could result in damage done to the pumps, e.g. dropping the pump from successively higher heights, will not be performed.

A6.2.1.a Sampling Duration. Four Leland Legacy pumps will be evaluated to determine the duration that each pump can sample at the required flow rate under moderate temperature and low humidity conditions (25 ºC, 30%) on a single battery charge. Four pumps will be allowed to operate using battery power until the battery charge decays such that they no longer function. The batteries will be charged for 15 hours, and the pumps will be connected to an electronic flow meter and a precision orifice in order to simulate the pressure drop of the Sioutas impactor (11 inches H_2O). The pumps will be allowed to run until the battery charge decays and the pumps stop functioning; flow rate for each pump will be logged electronically throughout the experiment.

A6.2.1.b Operation in Extreme Temperature/Humidity. Four Leland Legacy pumps will be outfitted with flow meters and precision orifi and allowed to discharge and charge as in

Section A6.2.1.a. The pumps will then be evaluated for 24 hrs on their (battery powered) operation in high temperature, moderate humidity (40 ºC, 60%), and high temperature, high humidity (40 ºC, 90%) atmospheres. Flow rate data will be logged electronically throughout the 24 hr period.

A6.2.1.c Sampling Performance at Different Pressure Loads. Four Leland Legacy pumps will be outfitted with flow meters and precision orifi and allowed to discharge and charge as in Section A6.2.1.a. A series of tests will be conducted in which the pumps will independently be connected to three different critical orifi, yielding pressure drops ranging from approximately 1 to 2 times that of the unsampled, substrate-loaded Sioutas personal cascade impactor (11 - 19 inches H_2O). For each test run, the pumps will be allowed to run until the battery charge decays and the pumps stop functioning; flow rate for each pump and overall sound level data will be logged electronically throughout the experiment.

A6.2.2 Task B: Sampling Efficiency Comparison

This task will focus on establishing the sampling efficiency of the PCIS as compared to more well-established reference samplers using a laboratory generated test aerosol in a well-mixed environmental chamber. This Task will involve four of each test and reference impactor samplers and will be repeated three times in order to measure inter- and intra-sampler variability.

Sampling efficiency comparison will be carried out by generating an aerosol of potassium chloride in Battelle's large environmental chamber (17.3 m^3) and allowing both the PCIS test and reference samplers to sample the chamber environment. The environmental chamber is constructed of aluminum and is equipped with a large fan to promote mixing. Four of the test Sioutas personal cascade impactors will be placed in close proximity of one another inside our environmental chamber, which will be maintained at well-mixed conditions. The impactors will be connected to their respective pumps through ports in the side of the chamber. The sampling pumps will be located outside the chamber, and will be powered using DC adapters plugged into A/C outlets. Four PEMs (2.5 µm cutpoint), four PM 2.5 FRMs, and four Battelle cascade impactor samplers will be placed similarly inside the chamber with their sampling inlets in close

proximity to the Sioutas' impactors, and their pumps either placed outside the chamber (if possible) or simply vented outside the chamber, where they will be powered by A/C outlets.

The test aerosol will consist of potassium chloride particles generated within the test chamber by aerosolizing a potassium chloride solution of known concentration with a commercially available nebulizer. The three parameters that will be varied in order to achieve the optimum test aerosol are: 1) nebulizer design, 2) atomizing air flow rate to the nebulizer, and 3) the potassium chloride solution concentration. During testing, the aerosol will be generated for a period of 1 to 4 hours at a flow rate that allows collection of a gravimetrically sufficient mass on each of the PCIS's impactor stages. The desired particle diameter size range for the aerosol is 0.1 to 10 µm.

The aerosol flow rate will be determined by running the nebulizer for a known time and measuring the initial and final liquid volume. Once a nebulizer is selected, a trial run will be conducted to ensure that the test aerosol is uniformly mixed throughout the environmental chamber, and confirm that enough mass is collected on each of the PCIS impactor stages. Sampling efficiency of the impactors will be evaluated gravimetrically for all stages in all test and reference samplers. Table A-1 shows the number and type of air samplers to be used to collect samples, the particle size cutpoint ranges, the number of samples to be collected for gravimetric analyses, and the pumps and flow rates for the samplers.

A6.2.3 Task C: Sampling Metals in Ambient Air

This task will focus on the ability of PCISs to collect a sufficient sample to detect metals in ambient air during a 48 hr sampling period. The results of the PCISs will be compared with results from collocated reference samplers.

Table A-1. Experiment Matrix for PCIS Sampling Efficiency Comparison

Sampler	Pump, Flow Rate	No. of Samplers in Chamber	Particle Diameter Cutpoints (µm)	No. of Samples for Grav. Anal.
Sioutas Cascade Impactor (PCIS)	Leland Legacy, 9 L/min	4	>2.5	4
			$1.0 and #2.5	4
			$0.5 and #1.0	4
			$0.25 and #0.5	4
			<0.25	4
Total				20
PEMS Environmental Monitor (Reference)	SKC, 10 L/min	4	#2.5	4
$PM_{2.5}$ FRM (Reference)	Internal, 16.7 L/min	4	#2.5	4
Battelle Cascade Impactor (Reference)	Gast, 12.5 L/min	4	>16	4
			$8.0 and #16	4
			$4.0 and #8.0	4
			$2.0 and #4.0	4
			$1.0 and #2.0	4
			$0.5 and #1.0	4
			<0.5	4
Total				28

Four test Sioutas personal cascade impactors and four PEMs (2.5 Fm cutpoint) will be placed in the chamber with their pumps located outside the chamber, as described in Section A6.2.2, Task B. Clean sample handling techniques for trace metals analysis will be used to load, and collect substrates from these samplers. Ambient air will flow through the well-mixed chamber at a rate of 1.0 ACH for a period of 48 hrs and will be sampled by the reference and PCIS samplers. At the beginning and end of the 48-hr sampling period, the pressure drop and

flow rate will be measured for all samplers. Substrates corresponding to the different particle size ranges will be analyzed for the metals shown in Table A-2 using X-ray fluorescence (XRF). Approximate instrument and method detection limits for these techniques are also listed in Table A-2.

A6.2.4 Task D: Sampler Ease of Use, Reliability, and Subject Acceptability/Compliance

This task will focus on qualitatively and semi-quantitatively establishing the burden human subjects associate with using the PCIS. A total of 5 - 10 non-smoking subjects will be recruited to wear the PCIS for a period of 48 hours and keep a simple time/activity diary for that period. Non-smoking subjects will be recruited to come to the Battelle laboratory to be fitted with the PCIS. Subjects will be instructed to wear the PCIS during all the activities they conduct for the next 48-hour period, with the exception of sleeping and showering/bathing. At bedtime, subjects will be instructed to put the PCIS on the nightstand and plug it into the A/C adaptor so that the pump will continue to sample their environment while they are sleeping. Likewise during showering/bathing, the subjects will be instructed to place the PCIS on the bathroom counter, or other suitable surface, with the pump still operating. At the end of the sampling period, subjects will return to the laboratory to turn in their pumps and completed time/activity diaries, at which time they will be asked to fill out a questionnaire to gather information about the pump's ease of operation, reliability, and their acceptance of the device. Ease of use and reliability will also be evaluated by Battelle laboratory technicians during sampler setup and return. The pumps will be equipped with small, data-logging multidirectional accelerometers that will measure and log occurrence and intensity of activity, and thus will provide an objective measurement of subject protocol compliance during the 48 hr sampling period. The subject's time/activity diary will be compared to the occurrence and intensity of activity logged by the accelerometer during the 48-hr period. At the beginning and end of the sampling period the pressure drop and flow rate of each sampler will be measured. Subjects will be paid for their participation in the study.

Table A-2. Instrument and Method Detection Limits for Metals Analyses using XRF

Metal	Instrument Detection Limit (ng/filter)	Approx. Method Detection Limit (ng/m^3)*
Al	64	2.5
Si	45	1.7
P	39	1.5
S	32	1.2
Cl	39	1.5
K	24	0.93
Ca	16	0.61
Ti	11	0.44
V	8.0	0.31
Cr	8.0	0.31
Mn	13	0.48
Fe	10	0.39
Co	6.8	0.26
Ni	6.8	0.26
Cu	6.8	0.26
Zn	8.0	0.31
Ga	17	0.66
Ge	16	0.61
As	14	0.53
Se	11	0.44
Br	10	0.39
Rb	11	0.44
Sr	18	0.70
Y	17	0.66
Zr	21	0.79
Mo	28	1.1
Pd	58	2.2
Ag	61	2.4

Table A-2. (Cont'd.) Instrument and Method Detection Limits for Metals Analyses using XRF

Metal	Instrument Detection Limit (ng/filter)	Approx. Method Detection Limit (ng/m^3)*
Cd	63	2.4
Sn	110	4.2
Sb	88	3.4
I	160	6.1
Ba	680	26
La	410	16
Hg	28	1.1
Pb	32	1.2

*Assume 48 hr sampling period, 9 L/min sampling flow rate

A6.3 Verification Schedule

Table A-3 shows the planned schedule of laboratory and field testing activities and the data analysis/reporting in this verification test. As shown in Table A-3, the pump testing is planned to begin in January 2006. The laboratory testing will be completed in April 2006 with the completion of the sampling of metals in ambient air. The human subject field testing will be conducted in April and May 2006. Report preparation will begin while the testing is in progress, and draft reports will be generated, reviewed, and revised in July 2006, and finalized in August 2006.

A7 QUALITY OBJECTIVES

This verification test will evaluate the PCISs on the basis of sampling efficiency (as compared to more well-established reference samplers), ability to measure detectable levels of metals in ambient air, ruggedness, ease of use, reliability, and acceptability to volunteer subjects.

Table A-3. Planned Verification Schedule

Month (Year)	Test Activity	
	Pump Testing Activities	**Pump Evaluation Parameters**
January (2006)	C Set up/install PCISs in constant temperature and humidity chamber (CTHC) C Select critical orifi to equal impactor pressure drop (11 inches H_2O) C Equip pumps with data logging flow meters C Measure pre- and post-experiment pressure drop and flow rate C Equip CTHC with data logging sound level meter	C Duration of operation (monitored via flow rate) on single battery charge at moderate temperature and low humidity conditions C Flow rate for 24 hrs of battery operation in high temperature, moderate humidity (40EC, 60%) and high temperature/high humidity (40EC, 90%) conditions C Flow rate and noise level for duration of operation (single battery charge) under three different pressure drops, ranging from 11 - 19 inches H_2O.
	Sampling Efficiency Comparison Activities	**Parameters for Comparison of PCISs to Reference Samplers**
February, March (2006)	C Set up/install PCISs in environmental chamber C Set up/install reference samplers in environmental chamber C Generate test KCl aerosol C Measure pre- and post-experiment pressure drop and flow rate C Determine mass associated with each particle size range	C Mass associated with each particle size range ($\mu g/m^3$) C Pre- and post-experiment pressure drop (inches H_2O) and flow rate (L/min)
	Sampling Metals in Ambient Air Activities	**Parameters for Comparison of PCISs to PEMs**
March, April (2006)	C Set up/install PCISs in chamber C Set up/install PEMs in chamber C Collect ambient air for 48 hours C Measure pre- and post-experiment pressure drop and flow rate C Analyze substrate filters for metals	C Pre- and post-experiment pressure drop (inches H_2O) and flow rate (L/min) C Target metal concentrations (ng/m^3) associated with each particle size range in 48-hour ambient air sample

Table A-3. (Cont'd.) Planned Verification Schedule

Month (Year)	Test Activity	
	Sampler Ease of Use, Reliability, and Subject Acceptability/Compliance Activities	**PCIS Evaluation Parameters**
April, May (2006)	C Recruit 5-10 subjects C Explain sampling protocol, basic pump operation, time/activity diary to each subject C Characterize pump/PCIS and equip with accelerometer; releast to subject C After 48-hour sampling period, characterize pump/PCIS, download accelerometer data C Have subject provide time/activity diary and written response to questionnaire C Pay subject for participation in study	C Pre-and post-experiment pressure drop (inches H_2O) and flow rate (L/min) C Qualitative subject acceptance and compliance with sampling protocol (questionnaire) C Semi-quantitative subject compliance with sampling protocol (compare gross accelerometer data with time/activity diary)
	Reporting	
January - July (2006)	C Prepare draft reports C Vendor review of draft reports C Revision of draft reports C Peer review of draft reports	
July, August (2006)	C Revision of draft reports C Submission of final reports for EPA approval	

Pump testing will be assessed using data logging flow meters, a sound level meter, and well mixed constant temperature and humidity chambers. The flow meters (TopTrak, Sierra Instruments) are calibrated annually by the Battelle Instrument Services Laboratory (ISL). The ISL is accredited by the American Association for Laboratory Accreditation in mass, temperature, flow, pressure, time frequency and humidity. The sound level meter (2238 Mediator, Bruel & Kjaer) is calibrated annually to a NIST-traceable standard by the manufacturer. The constant temperature and humidity chambers (1.2 m^3, Webber Manufacturing) are calibrated annually by the manufacturer's service technician, in situ at Battelle.

Sampling efficiency, including precision from replicate samplers, will be assessed from comparisons of gravimetric samples collected using reference samplers and PCISs. To ensure the quality of the gravimetric analyses, all gravimetric analyses will be performed in Battelle's constant temperature and humidity microbalance laboratory. The microbalance laboratory is kept at 22 ± 1EC and 52 ± 2.5% relative humidity per 24 hours. All balances will be calibrated against a NIST-traceable reference standard. Routine quality control measurements, as described in Section B5, will be made to ensure accurate operation of the balances. Flow rate measurements will be performed using a primary gas flow piston calibrator (e.g., DryCal DC-Lite, Bios International), the calibration of which is performed by the manufacturer, an ISO-17025 accredited laboratory. In the ambient air task where metals analyses will be performed, flow rates will be measured using a soap bubble (M-30 Mini-Buck, A.P. Buck Inc.) primary gas flow calibrator, which has all-plastic wetted parts, and will be less likely to introduce metal contamination to the substrates. The Mini-Buck calibrators are calibrated annually by the manufacturer. The pressure drop measurements will be performed using a Magnehelic gauge, which is calibrated annually to a NIST-traceable standard by the Battelle ISL.

The ambient air sampling task of this verification test will include metals analyses using XRF. The quality of the metals analyses will be assured by adherence to acceptance accuracy and precision criteria for quality assurance (QA) standards, laboratory replicates, and National Institute of Standards and Technology (NIST) standard reference materials (SRMs); these acceptance criteria are given in Section B5.

Reliability, ease of use, and subject acceptability will be determined qualitatively by subjects completing a self-administered questionnaire about their experience using the PCIS after their participation in the field study portion of the test. Incongruous or confusing responses will be reviewed with the participants at the time of completion so as to assure the quality of the responses. Subject compliance will be determined semi-quantitatively by comparing the subject's time/activity diary with the occurrence and intensity of movement logged by the accelerometer attached to the subject's pump.

Performance evaluation (PE) audits will be conducted to ensure adherence to quality control requirements and to assure the data quality for the verification test. Section C1 describes the activities and acceptance criteria for the PE audit.

These QA/QC requirements will be augmented by a Technical Systems Audit (TSA), carried out by Battelle. The EPA Quality Manager also may conduct an independent TSA, at her discretion.

A8 SPECIAL TRAINING/CERTIFICATION

Documentation of training related to technology testing, field testing, data analysis, and reporting is maintained for all Battelle technical staff in training files at their respective locations. The Battelle Quality Manager may verify the presence of appropriate training records prior to the start of testing. Battelle technical staff will have a minimum of a bachelor's degree in science/engineering or have equivalent work experience. Staff performing the gravimetric determinations in Task B will have been trained and be qualified to perform mass measurements at low microgram levels.

A9 DOCUMENTATION AND RECORDS

The records for this verification test will be contained in the test/QA plan, chain-of-custody (CoC) forms, laboratory record books (LRB), data collection forms, electronic files (both raw data and spreadsheets), and the final verification report. All of these records will be maintained in the Verification Testing Coordinator's office during the test and will be transferred to permanent storage at Battelle's Records Management Office at the conclusion of the verification test. All Battelle LRBs are stored indefinitely, either by the Verification Testing Coordinator or Battelle's Records Management Office. EPA will be notified before disposal of any files. Section B10 gives further details regarding the data recording practices and responsibilities.

All written records must be in permanent ink. Any corrections to notebook entries, or changes in recorded data, must be made with a single line through the original entry. The correction is then to be entered, initialed, and dated by the person making the correction. A brief explanation will be written in next to all non-obvious corrections. In all cases, strict confidentiality of data from each vendor's technology, and strict separation of data from different technologies, will be maintained. Separate files (including manual records, printouts, and/or electronic data files) will be kept for each technology being verified.

SECTION B

MEASUREMENT AND DATA ACQUISITION

B1 EXPERIMENTAL DESIGN

This test will evaluate a variety of performance parameters of the Leland Legacy pump (alone) and the combination PCIS, which consists of the Sioutas Personal Cascade Impactor coupled to the Leland Legacy pump, under realistic operating conditions. Specifically, the pump will be evaluated for the following performance parameters:

- Sampling Duration
- Operation in Extreme Temperature/Humidity
- Sampling Performance at Different Pressure Drops

The PCIS will be evaluated for the following performance parameters:

- Comparability of Sampling Efficiency
- Ability to Collect Detectable Levels of Metals in Ambient Air
- Operational Factors (i.e., Ease of Use, Reliability, etc.)
- Subject Acceptability/Compliance

When designing a human exposure assessment study, it is important to understand the limitations of the field sampling equipment. To reduce subject burden and increase target pollutant detection limits, a personal sampling pump should be able to sample for a long period of time (> 24 hours) without requiring a battery recharge. Considering human exposure field studies often take place during the summer months, these pumps should also be rugged enough to operate in hot, humid weather.

As personal sampling pumps are used in the field, the substrates become loaded with particles and the pressure drop of the personal cascade impactor may increase, causing the pump to work harder to sample at the same flow rate. For this reason, pump performance in terms of flow rate will be monitored while the pumps sample under increasing pressure drop levels ranging from circa 1 to 2 times the pressure drop of an unsampled, substrate-loaded Sioutas

personal cascade impactor. Again, time and magnitude of flow rate fluctuations, and termination of operation will be summarized for each pump. Subjects have historically complained about how noisy personal sampling pumps are. Sound level data for the group of four pumps will also be measured in decibels and logged to a file during the testing of the pump performance under increasing pressure drop loads.

It is important to characterize newly introduced technology and compare it to more well established similar technologies that already have a body of human exposure data associated with them. The sampling efficiency of the PCIS will be compared to that of several reference samplers and comparisons will be reported as a relative percent difference of the means. Reference and test samplers will be co-located in an environmental chamber where they will sample a test KCl aerosol for a defined period of time. Sampling efficiency determinations will be made gravimetrically for all stages in all impactors. The reference samplers employed in this comparison include four $PM_{2.5}$ FRMs, four PEMs (2.5 µm cutpoint), and four Battelle cascade impactors. This Task will involve four of each test and reference impactor samplers and will be repeated three times in order to measure inter- and intra-sampler variability.

The $PM_{2.5}$ FRM is the recognized standard for the gravimetric determination of $PM_{2.5}$. The FRM method involves sampling of ambient air at 16.7 L/min to collect particles #2.5 µm in diameter onto a 37 mm polytetrafluoroethylene (PTFE) filter. The PEM is a lightweight personal sampling device consisting of a single impaction stage that, like the FRM, collects particles #2.5 µm in diameter onto a 37 mm PTFE filter. The PEM requires a personal sampling pump sampling at 10 L/min. The PEM will be used as a reference since it is a well established sampler that has been extensively used for personal PM exposure estimates,[4-20] and can be worn in a fashion similar to the PCIS, thus allowing a more direct comparison of PM exposure than the FRM allows.

The Battelle cascade impactor is a seven-stage particle sampler used to determine particle size distribution and particle mass concentration. The first six stages of the BCI consist of a series of nozzles each combined with a single glass slide to which a film of suitable impaction grease or water-based lubricant is applied (to prevent particle "bounce"). The geometry of each stage, combined with the controlled airflow through the device (12.5 L_{air}/min) provide for aerosol cut-points of 16, 8, 4, 2, 1, and 0.5 µm. A backup filter is used to collect particles smaller than this size. The Battelle cascade impactors are suitable as reference samplers because gravimetric results from the two lowest cutpoints, the 0.5 and 1.0 Fm stages, can be directly compared with results from those same PCIS cutpoints.

Inter-sampler precision will be determined from comparisons of the gravimetric analysis for the four replicate sets of samples collected for each test and reference impactor sampler during the sampling efficiency comparison test. Intra-sampler precision will be determined from the gravimetric data collected for each test and reference sampler for each of the three times the sampling efficiency comparison test will be conducted.

Ability to detect metals in ambient air will be determined from the analysis of the reference and test sampler substrates for metals content. The number of target metals with concentrations above the method detection limit will be reported for the 2.5 µm stage for the PEMs, and separately for each of the stages for the PCISs. In cases where metals concentrations are above the method detection limit, the results (ng/m^3) for the stages will be summed for each PCIS and compared with those obtained for each PEM.

Historically, personal air sampling is vulnerable to sample selection bias because it imposes a substantial burden on the subjects, making it difficult to recruit a representative sample of subjects that will comply with the air sampling protocol.[21] Because of these difficulties, this verification test will not attempt to assess the performance of the PCIS using human subjects. Rather, this verification test will use human subjects to evaluate the PCIS in

terms of ease of use, reliability, and acceptability. In Task D, each subject's pump will be equipped with a small (<18 g), unobtrusive accelerometer (AW-64, Mini Mitter Co., Inc.) that will log movement occurrence and intensity to an electronic file throughout the 48 hr field sampling period. Subject compliance will be determined semi-quantitatively by comparing the subject's time/activity diary with the data logged by the accelerometer attached to the subject's pump. Long periods of complete inactivity (> 2 hrs) that take place during active periods described in the time/activity diary will be summarized for each subject.

Reliability, ease of use, and subject acceptability will be determined qualitatively by having subjects complete a self-administered questionnaire about their experience using the PCIS after their participation in the field study portion of the test. Incongruous or confusing responses will be reviewed with the participants at the time of completion so as to assure the quality of the responses.

Operational factors such as time taken to configure the pump, maintenance needs, how easy it is to clean the impactor and load and recover the substrates, and reliability will be determined by the laboratory technician that configures the PCIS, records of needed maintenance, and the pump's run time during the field study.

B1.1 Test Procedures

The following sections describe the test procedures that will be used to evaluate each of the PCIS performance parameters listed above.

All of the pump evaluation experiments will be performed in a constant temperature and humidity chamber used to simulate moderate and extreme conditions and equipped with feedthroughs that will allow the collection and logging of flow rate data chronologically for each pump. Each of the tests conducted in Task A will involve four pumps and will be repeated three times in order to measure inter- and intra-pump variability. The flow rate will be monitored using a digital flow meter that has a 0-5V analog output that will be logged to an electronic file using LabView (ver. 6) software. This file will be reviewed after the experiments, and the time and magnitude of flow rate fluctuations, the time at which the flow rate decayed by

>10%; (e.g., from 9 L/min to <8.1 L/min for the Leland Legacy pump), and the time at which the pump stopped operating, will be recorded in the data log file.

B1.1.1 Sampling Duration

The sampling duration of each PCIS will be evaluated by monitoring the flow rate chronologically during sampler operation from a single 15-hour battery charge. The time and magnitude of flow rate fluctuations, the time at which the flow rate decayed by >10%; (e.g., from 9 L/min to <8.1 L/min for the Leland Legacy pump), and the time at which the pump stopped operating, will be summarized from the flow rate data log file. These measurements, along with the pump identification code, date, and time, will be recorded either electronically or in the LRB.

B1.1.2 Ruggedness: Sampling Performance Under Different Temperature, Humidity and Pressure Load Conditions

The flow rate for each pump will be logged chronologically during the high temperature and humidity and increasing pressure drop experiments described in Sections A6.2.1.B and A6.2.1.C. The time and magnitude of flow rate fluctuations, the time at which the flow rate decayed by >10%; (e.g., from 9 L/min to <8.1 L/min for the Leland Legacy pump), and the time at which the pump stopped operating, will be summarized from the flow rate data log file. These measurements, along with the pump identification code, date, and time, will be recorded either electronically or in the LRB.

B1.1.3 Comparability

The comparability of each PCIS will be evaluated in Task B, Section A6.2.2, by comparison of sampling efficiency results for similar particle diameter ranges and for the entire range monitored to those obtained for the reference samplers during simultaneous fixed-site sampling of a laboratory generated KCl test aerosol. The number of samples intended for gravimetric analyses is shown in Table A-2. To limit potential bias between the PCIS and the

reference sampler's results, the devices will be run simultaneously in a well-mixed environmental chamber, and samplers will be co-located in a 2 m^2 area.

B1.1.4 Ability to Collect Metals in Ambient Air

The ability of the PCIS to collect metals in ambient air will be determined in Task C, Section A6.2.3, by analyzing the substrates from the individual stages using XRF according to the guidelines specified in EPA Compendium Method IO-3.3[1]. These results will be compared to those obtained for the PEMs samplers. Clean sampling techniques for trace metals analysis will be used to minimize contamination of the low levels expected to be found in these samples. Blank substrates will also be analyzed to quantify any metals contamination of the substrates.

The flow rate for each PCIS will be measured at the beginning and at the completion of each of the tests in Tasks B-D. The flow rate will be measured using a primary flow piston or bubble flowmeter. These measurements, along with the PCIS identification code, date, and time, will be recorded in the LRB.

B1.1.5 Operational Factors

Operational factors such as maintenance needs, consumables used, ease of use, repair requirements, etc., will be evaluated based on observations recorded by Battelle laboratory staff, and in some cases by the human subject volunteers. Battelle staff will record these observations, along with the PCIS identification code, date, and time in the LRB. Examples of information to be recorded in the LRB include use or replacement of any consumables; the effort or cost associated with maintenance or repair; vendor effort (e.g., telephone consultation time or time on site) for repair or maintenance; the duration and causes of any PCIS down time; and observations about ease of use and portability of the PCIS. These observations will be summarized to aid in describing PCIS performance in the verification report on each PCIS.

B1.1.6 Subject Acceptability/Compliance

At the end of the 48-hr human subject field sampling period, subjects will return to the laboratory and fill out a questionnaire to gather their impressions on the PCISs burden, reliability, ease of operation, and their own protocol compliance. The questionnaire is included as Appendix A to this test/QA plan.

Subjects will keep a simple time/activity diary during the 48 hr sampling period. Each subject's pump will be equipped with an accelerometer that will log the occurrence and intensity of movement to a data file. At the end of the sampling period, subject compliance will be determined semi-quantitatively by comparing the subject's time/activity diary with the data logged by the accelerometer attached to the subject's pump. Long periods of complete inactivity (> 2 hrs) that take place during active periods described in the time/activity diary will be summarized for each subject. The time/activity diary is included as Appendix B to this test/QA Plan.

B1.2 Statistical Analysis

The statistical methods and calculations used for evaluation of the quantitative performance parameters are described in the following sections.

B1.2.1 Comparability of Sampling Efficiency

The comparability of the PCISs will be assessed in terms of the relative percent difference (*RPD*) of the mean of four replicate PCIS measurements with respect to the mean of the four replicate measurements of the reference samplers , using Equation 1:

$$RPD = \frac{\left|C_{PCIS} - C_{REF}\right|}{C_{REF}} \times 100\% \qquad (1)$$

where:

C_{PCIS} = mean particle or metal mass concentration (µg/m^3) measured by the PCIS

C_{REF} = particle or metal mass concentration (µg/m^3) measured by reference sampler.

The *RPD* will be calculated and reported separately for comparisons of each PCIS with the $PM_{2.5}$ FRM and the PEM, as well as for the corresponding stages of the Battelle impactor.

B.1.2.2 Variability

The inter-pump/sampler variability (*V*) for Tasks A - C will be assessed in terms of relative standard deviation from the mean of four replicate pumps/samplers, according to Equation 2:

$$V = \frac{1}{n}\sum_{i=1}^{n} C_i \pm \frac{S.D.}{\left[\frac{1}{n}\sum_{i=1}^{n} C_i\right]} \times 100 \qquad (2)$$

where:

C_i = duration of pump operation for pump *i*, or particle or metal mass concentration (µg/m^3) for sampler *i*

S.D. = standard deviation of the sample (n=4)

The intra-pump/sampler variability (V_i) will be assessed in terms of relative standard deviation from the mean of three replicate test runs, according to Equation 3:
where:

$$V_i = \frac{1}{n}\sum_{j=1}^{n} C_{i,j} \pm \frac{S.D._i}{\left[\frac{1}{n}\sum_{j=1}^{n} C_{i,j}\right]} \times 100 \qquad (3)$$

$C_{i,j}$ = duration of pump operation for pump *i*, or particle or metal mass concentration (µg/m^3) for sampler during Test Run *j*

SD_i = standard deviation of the sample (n=3).

B.1.2.3 Metals Detection

The collection ability of the PCISs for a given metal will be judged against the analytical method detection limits for each target analyte divided by the volume of air sampled by the PCIS during a 48-hour period. The analytical method detection limits (ng/filter) are determined according to EPA Compendium Method IO-3.3[1], and are presented in Table A-3. The concentration (C_M) of the PCIS (ng/m^3) for a given metal in ambient air will be calculated using Equation 4:

$$C_M = \frac{S_M}{F_A \times T} \times 1000 \qquad (4)$$

where:

S_M = concentration (ng/filter) of the metal in the collected substrate sample

F_A = average flow rate (L/min) during the 48-hour sampling period

T = time period air was sampled (min)

Target metals will be reported as detectable if C_M is greater than the analytical detection limit. All detectable analytical results for the test and reference sampler substrates collected during Task B will be presented and compared.

B1.3 Reporting

The statistical comparisons described above will be conducted for the PCIS technology being tested, and information on the operational parameters will be compiled and reported. The data for this technology will not be compared to data from any other technologies other than the reference samplers shown in Table A-1. A verification report will be prepared for the PCIS technology tested that presents the test procedures and test data, as well as the results of the statistical evaluation of those data.

Operational aspects of the PCISs will be recorded by both testing staff and study participants. Testing staff will record their observations during the chamber tests and those observations will be summarized in the verification report. For example, consumables used,

repairs and maintenance needed, and the nature of any problems will be presented in the report. Study participants will record their responses to the questions regarding ease of use, reliability, and portability at the conclusion of their participation in the human subject field test. The questionnaire data for all of the participants will also be summarized in the report. A comparison of the time/activity diary with the accelerometer data will be performed for all of the participants and summarized in the report. Each verification report will briefly describe the ETV program, the AMS Center, and the procedures used in verification testing. The results of the verification test will be stated quantitatively, without comparison to any other technology tested, or comment on the acceptability of the PCIS's performance. The draft verification report will first be subjected to review by the technology vendor, then revised and subjected to a review by EPA and other peer reviewers. The peer review comments will be addressed in further revisions of the report, and the peer review comments and responses will be tabulated to document the peer review process. The reporting and review process will be conducted according to the requirements of the AMS Center QMP.[2]

B2 SAMPLING METHODS

Sampling will be conducted for four specific tasks for this verification: A) Pump Testing, B) Sampling Efficiency Comparisons, C) Sampling Metals in Ambient Air, and D) PCIS Ease of Use, Reliability and Subject Acceptance. In Tasks A-C, operation of the pump/PCIS, will be performed by Battelle staff according to the PCIS manufacturer's recommendations. In Task D, Battelle staff will instruct study participants on personal sample collection, including how to operate the pump using the A/C adaptor, for the 48-hr human subject field study, but ultimately, no supervision by Battelle staff will be performed during these samplings. The inlet tube for all personal samples will be clipped to the breast pocket area of the subject's shirt on the dominant hand side. The inlet tubes for the fixed site sampling will be approximately the same length as that used for the personal sampling, and will be co-located in a 2 m^2 area.

For Task B, each impactor sampler will be outfitted with pre-conditioned and pre-

weighed substrates. The substrate gravimetric determinations will be performed based on the guidelines outlined in the Quality Assurance Guidance Document 2.12, "Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods".[22] Gravimetric determinations will be completed within 10 days of sample collection.

For Task C, each impactor sampler will be outfitted with pre-conditioned substrates that are not weighed. Clean sampling techniques for trace metals analyses will be used to avoid contamination of the substrates. The collection of the samplers' substrates into filter cassettes will be conducted exclusively by Battelle staff according to the vendor's instructions within 1 hour of the completion of the sampling period. Substrates will be shipped via overnight carrier to Chester LabNet for XRF analysis according to the guidelines outlined in EPA Compendium Method IO-3.3.[1]

For Tasks B and C, if a pump failure occurs prior to the time at which the sampling period is <80% completed, the pump will be replaced and sampling will continue for the required period; this event, along with the sampler and pumps' identifications, will be described in the LRB. If the sampling period is $80% completed and a pump failure occurs, the test will be stopped and the sample will be processed as is, taking the shorter sampling duration into account during the gravimetric or metals concentration data reduction. Field blanks will be processed at an overall rate of 10% of the real samples. In addition, independent audits of sampling procedures will be carried out by Battelle as part of the Technical Systems Audit procedure (Section C1.2).

B3 SAMPLE HANDLING AND CUSTODY

For gravimetric determinations, all air substrate samples will be entirely in the custody of Battelle from sample collection through sample recovery and analysis. For metals analyses, air substrate samples will be recovered into filter cassettes and shipped in insulated shipping coolers, containing blue ice and capable of maintaining a temperature of below 25 EC, via overnight carrier to Chester Lab Net with proper chain-of-custody (CoC) documentation. Sample custody will be documented throughout collection, recovery, and analysis of the samples, using

standard CoC forms that document sample custody transfer according to the Battelle SOP MDAS.I-009-Draft. Each CoC form will be signed by the person relinquishing samples once that person has verified that the CoC form is accurate. Upon receipt of samples in order to perform gravimetric determinations or XRF analyses, CoC forms will be signed by the person receiving the samples once that person has verified that all samples identified on the CoC are to be processed that day. Any discrepancies will be noted on the form and the sample receiver will immediately contact the Verification Testing Coordinator to report missing, broken, or compromised samples. Copies of all CoC forms will be delivered to the Verification Testing Coordinator, and maintained with the test records.

B4 ANALYTICAL METHODS

All XRF determinations will be performed by Chester LabNet according to the guidelines specified in EPA Compendium Method IO-3.3.[1] Chester LabNet is responsible for providing the analytical instrumentation, calibrating that instrumentation based on the guidelines specified in EPA Compendium IO-3.3, performing method QA/QC (see Section B5.2), and maintaining calibration records for any instrumentation used. A summary of the calibration verification and quality control data for XRF determinations will be provided in the report.

Gravimetric analyses will be performed based on guidelines specified in EPA's $PM_{2.5}$ method[22] for monitoring ambient air. Battelle is responsible for providing the constant temperature and humidity balance room, and calibrating the balances based on the guidelines specified in the "Filter Preparation and Analysis" section of the $PM_{2.5}$ method, performing QA/QC (see Section B5.3), and maintaining calibration and maintenance records for instrumentation used. A summary of calibration and quality control data for the gravimetric determinations will be provided in the report.

B5 QUALITY CONTROL

Fixed site air sampling and gravimetric analyses will be performed based on guidelines specified in EPA's $PM_{2.5}$ method[22] for monitoring ambient air, and metals analyses will be

performed based on guidelines specified in EPA's Compendium Method IO-3.3.[1] These measurements will be subject to the data quality control requirements summarized in Table B-1.

B5.1 Flow Rate Checks

The flow rate of each reference sampler and each PCIS will be measured at the beginning of each test in Tasks B - D. If, at the beginning of each test, the measured flow rate exceeds a 10% variance from the manufacturer's recommended values, the reference sampler or PCIS will be removed from the test and repair or maintenance will be performed according to the vendor's recommendations. The sampler will be re-included in the test once the initial parameters fall within the 10% variance. The flow rate of each reference sampler and each PCIS will also be measured at the end of each sampling period and recorded. If the flow rate exceeds a 10% variance from the manufacturer's recommended values, the data from the reference sampler or PCIS will be flagged.

B5.2 Pressure Drop Checks

The pressure drop of each PCIS will be measured at the start of each sampling period for Tasks B-D. If the measured pressure drop is less than 11 inches H_2O or exceeds 16 inches H_2O, the PCIS will be removed from the test and leak checks, repair or maintenance will be performed according to the vendor's recommendations. The PCIS will be re-included in the test once the initial pressure drop falls within the 11 - 16 inches H_2O range. The pressure drop of each PCIS will also be measured at the end of each sampling period and recorded. If the pressure drop falls outside of the 11 - 16 inches H_2O range, the data will be flagged.

B5.3 Field Replicates

The Sampling Efficiency Comparison test will include the collection of four replicates for test and reference samplers to establish the variability of the test and reference samplers. Relative standard deviation from the mean must fall within 30%, or data will be flagged, and the well-mixed state of the chamber will be verified.

Table B-1. Quality Control Requirements for Verification Tests

QC Parameter	Addressed By	Required Performance
Reference Sampler and PCIS Flow Rate	Measure flow rate at the beginning and end of each test	Beginning results within 10% of vendor's recommended value; otherwise remove sampler and troubleshoot; ending results outside 10% data will be flagged
PCIS Pressure Drop	Measure pressure drop at the beginning and end of each test	Beginning results $11 and #16 inches H_2O; otherwise remove sampler and troubleshoot; ending results outside this range will be flagged
Field Replicates	Samples recovered from co-located samplers	Relative standard deviation #30%, otherwise chamber will be analyzed to prove well-mixed condition, data will be flagged
Field blanks	Substrates handled in all ways like real sample except no sampling performed, collected at a frequency of 10% of real samples	If blank <10% of sample's metal concentration or <10 x MDL, subtract blank from samples; if blank >10% of sample's metal concentration, data will be flagged, source of contamination found/eliminated
Metals matrix blanks	Analyze blank substrate every time new batch of real samples is analyzed	If blank <10% of sample's metal concentration or <10 x MDL, subtract blank from samples; if blank >10% of sample's metal concentration, data will be flagged, source of contamination found/eliminated
Metals measurement accuracy	Analyze QS[a] sample every analytical run	Results within 10% of expected value, otherwise terminate analysis, determine cause of QS failure; repeated failures require a recalibration of any excitation condition(s) not meeting the required limits and reanalysis of the samples associated with the failed QS
Metals measurement accuracy	Analyze SRM[b] weekly	Results within NIST certified uncertainty, otherwise terminate analysis, recalibrate the excitation condition in which the failure occurs, reanalysis of the samples associated with the failed SRM.

Table B-1. (Cont'd.) Quality Control Requirements for Verification Tests

QC Parameter	Addressed By	Required Performance
Metals measurement accuracy	Analyze independently prepared standard (blind PES[c]) every 20 samples	Results within 20% of expected value, otherwise recalibrate and re-test; if problem persists data will be flagged
Gravimetric measurement accuracy and precision	Measure mass reference standards prior to, after every 10 substrates, and at the completion of each balance-use session	±2 µg of true value; otherwise service balance
Substrate stability	Re-weigh 10% of previous balance-use session's samples	±15 µg for blank substrate ±30 µg for exposed substrate; otherwise check temperature and humidity logs

[a] QS - quality assurance standard
[b] SRM - NIST standard reference material
[c] PES - performance evaluation standard

B5.4 Field Blanks

To verify that metals results are real and not due to contamination, field blanks will be processed at a rate of 10% of the real samples collected. Field blank substrates will be pre-cleaned (if needed), stored, and treated in all ways like a real sample, with the exception that no sampling will be performed on these substrates. If the field blanks show contamination that is less than 10% of the metal concentration found in the real samples or less than ten times the MDL, then the results for the field blanks will be subtracted from the real samples. If the field blanks show contamination that is greater than 10% of the samples's metal concentration the results for the laboratory matrix blank will be examined. If the laboratory matrix blanks show no contamination, sample collection materials will be examined until the source of contamination is found and/or is eliminated. If the contamination cannot be eliminated the data will be flagged and the impact will be discussed in the report.

B5.5 Checks of Metals Analysis Accuracy

The calibration of the XRF is performed only when a change in fluorescers, x-ray tubes or detector is made, or a serious malfunction occurs. Calibration verification Quality Assurance Standards (QS), or multi-element thin film vapor-deposited standards on mylar, will be analyzed every analytical run as a check of the instrument's operation. If the results are not within 10% of the expected value, the analysis will be terminated and the cause of the QS failure will be determined. Repeated failures will require a recalibration of any excitation condition not meeting the required limits, and reanalysis of the samples associated with the failed QS will be performed.

NIST-certified SRMs will be analyzed weekly alongside the samples. If the percent recovery for any of the target metals in the SRM falls outside the NIST certified uncertainty, analysis will be terminated and the cause of the SRM failure will be determined. The excitation condition in which the failure occurs will be recalibrated and the samples associated with the failed SRM will be reanalyzed. The percent recovery (R) of a given metal will be calculated using Equation 5:

$$R = \frac{C_M}{C_T} \times 100\% \quad (5)$$

where:

C_M = measured concentration (µg/cm^2)
C_T = theoretical or certified concentration (µg/cm^2)

Blind PE samples will be analyzed as part of the PE audit (see Section C1) to assess the quality of the metals measurements made in this verification test. If the percent recovery measured for any target metal in the PE sample falls outside the 80-120% range, the instrumentation will be examined and serviced or maintained as needed, and the PE samples will be re-analyzed. If the PE sample results continue to fall outside the acceptable range, the data will be flagged.

B5.6 Metals Matrix Blank Samples

A laboratory matrix blank, or blank substrate, will be analyzed with every new batch of real samples. If laboratory matrix blanks show detectable contamination that is greater than 20% of the detectable metal concentration in the samples being analyzed the sample storage containers and collection materials will be examined until the source of contamination is found and corrected if feasible. For example, substrates may require pre-cleaning prior to being used for sampling. If the contamination cannot be eliminated the data will be flagged.

B5.7 Gravimetric Measurement Checks

The calibration of the analytical balances will be checked using NIST-traceable mass reference standards that span the range of weights to be measured, i.e., 100-300 mg, prior to and at the completion of performing any gravimetric determinations. Balances will also be checked with these weights after the measurement of every ten real samples. If the measurement of the certified weights falls outside ± 2 µg, the balance will be recalibrated or repaired by a certified technician prior to its use for this test.

The stability of the substrates will also be checked by re-weighing 10% of the samples from the previous batch of samples. If the blank substrates do not fall within ±15 µg of the previously made measurements and/or the exposed substrates don't fall within ± 30 µg of the previously made measurements, the temperature and humidity logs for the balance room will be examined. If temperature and humidity inside the balance room prove stable, the data will be flagged, and other sources responsible for the differences will be investigated.

B6 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE

Operation, and maintenance of the reference samplers and each PCIS will be performed by Battelle staff according to the vendor's written instruction. The equipment used for measuring continuous flow rate and pressure drop is inspected annually and maintained by Battelle's ISL, which is accredited by the American Association for Laboratory Accreditation. Both the piston and bubble flowmeters used for measuring discrete flow rate are calibrated

annually by the manufacturer. The sound level meter is also calibrated annually by the manufacturer. The constant temperature and humidity chambers are calibrated in situ at Battelle by the manufacturer's field technician. The balances used to perform the gravimetric determinations are calibrated annually, inspected and maintained by a qualified technician. The XRF instruments are inspected prior to use; routine maintenance is performed on these instruments according to the manufacturer's recommendations and recorded in the LRB assigned to that instrument.

B7 INSTRUMENT/EQUIPMENT CALIBRATION AND FREQUENCY

The PCISs require no calibration, but records of the pump flow rate measured for each PCIS will be kept. Calibration of the flow rates of each reference sampler will be conducted within one week prior to the beginning of testing according to the vendor's written instructions. The equipment used for measuring flow rate and pressure drop is calibrated annually to a NIST-traceable standard by Battelle's ISL. These calibration records are kept by the ISL. The balances used to perform the gravimetric determinations are checked with certified weights prior to the user collecting data with the balance. These calibration checks are recorded in the LRB at the time of the check. The XRF instruments' calibration is checked each run using a QS standard, and a blind PES after every 20 samples. These calibration records are a part of the data file that is generated for each XRF run.

B8 INSPECTION/ACCEPTANCE OF SUPPLIES AND CONSUMABLES

All materials, supplies, and consumables will be ordered by the Verification Test Coordinator or designee. Where possible, Battelle will rely on sources of materials and consumables that have been used previously as part of ETV verification testing without problems. Battelle will also rely on previous experience or recommendations from EPA advisors, or PCIS vendors.

B9 NON-DIRECT MEASUREMENTS

Data published previously in the scientific literature will not be used during this verification test.

B10 DATA MANAGEMENT

Various types of data will be acquired and recorded electronically or manually by Battelle and study participants during this verification test. Table B-2 summarizes the types of data to be recorded. All maintenance activities, repairs, calibrations, and operator observations relevant to the operation of the PCISs will be documented by Battelle in the LRBs. A separate LRB will be maintained for each participating technology. Results from the metal determinations will be compiled and submitted to the Verification Test Coordinator.

Records received by or generated by any Battelle staff during the verification test will be reviewed by the Verification Test Coordinator or the Verification Testing Leader within two weeks of receipt or generation, respectively, before the records are used to calculate, evaluate, or report verification results. The review will be documented by the person performing the review by adding his/her initials and date to the hard copy of the record being reviewed. In addition, any calculations performed by Battelle staff will be spot-checked by Battelle technical staff to ensure that calculations are performed correctly. Calculations to be checked include any statistical calculations described in this test/QA plan. The data obtained from this verification test will be compiled and reported and the results for PCISs will not be compared with results from other impactors other than the reference impactors included in this test.

Among the QA activities conducted by Battelle QA staff will be an audit of data quality. This audit will consist of a review by the Battelle Quality Manager of at least 10% of the test data. During the course of any such audit, the Battelle Quality Manager will inform the technical staff of any findings and any immediate corrective action(s) that should be taken. If serious data quality problems exist, the Battelle Quality Manager will notify the Battelle AMS Center Manager, who has the authority to direct testing staff to stop work. Once the assessment report has been prepared, the Verification Test Coordinator will ensure that a response is provided for

each adverse finding or potential problem, and will implement any necessary follow-up corrective action(s). The Battelle Quality Manager will ensure that follow-up corrective action(s) has been taken.

Table B-2. Summary of Data Recording Process

Data to Be Recorded	Where Recorded	How Often Recorded	By Whom	Disposition of Data
Dates, times, and details of each test procedure, PCIS maintenance, down time, etc.	ETV test LRB	Start/end of each experiment for Tasks A-C	Battelle	Summarized and incorporated into verification report
Initial and final flow rate, pressure drop	Sampler Run Data Sheet	Start/end of each experiment for Tasks A-D	Battelle	Incorporated into verification report
Pre- and Post-sampling substrate mass	Substrate Preparation and Analysis Data Sheet	Start/end of gravimetric analyses	Battelle	Incorporated into verification report
XRF QS calibration verification information	XRF data file	Prior to use of XRF to quantify metals content of substrates	Chester LabNet	Incorporated into verification report
Subject time/activity diary	Hand-written on time/activity diary form	Recorded continuously throughout 48 hr field study	Participant	Summarized in the verification report
Subject questionnaire responses	Hand-written on questionnaire form	At the completion of the field study for each participant	Participant	Summarized in the verification report

SECTION C

ASSESSMENT AND OVERSIGHT

C1 ASSESSMENTS AND RESPONSE ACTIONS

Every effort will be made in this verification test to anticipate and resolve potential problems before the quality of performance is compromised. One of the major objectives of this test/QA plan is to establish mechanisms necessary to ensure this. Internal quality control measures described in this test/QA plan, which is peer reviewed by a panel of outside experts, implemented by the technical staff and monitored by the Verification Testing Coordinator, will give information on data quality on a day-to-day basis. The responsibility for interpreting the results of these checks and resolving any potential problems resides with the Verification Testing Coordinator. Technical staff have the responsibility to identify problems that could affect data quality or the ability to use the data. Any problems that are identified will be reported to the Verification Testing Coordinator, who will work with the Battelle Quality Manager to resolve any issues. Action will be taken to control the problem, identify a solution to the problem, and minimize losses and correct data, where possible. Independent of any EPA QA activities, Battelle will be responsible for ensuring that the following audits are conducted as part of this verification test.

C1.1 Performance Evaluation Audit

A performance evaluation (PE) audit will be conducted at least once during the verification test. This PE audit will include checks of the reference sampler flow rates, checks of the analytical balance, and blind PESs for metals analyses.

A flow audit of reference samplers will be conducted using a flow standard that is independent of that used to calibrate the reference samplers. If the measured flow rate exceeds a 10% variance from the manufacturer's recommended values, any suspect data will be flagged, the reference sampler will be recalibrated, and sampling will be repeated if feasible.

Audits of the analytical balance will be conducted using certified mass standards independent of those used for calibration or routine calibration checks. If the audit measurement of the certified weights falls outside of ±2 µg, the balance will be recalibrated or repaired by a certified technician, suspect data will be flagged, and suspect gravimetric analysis will be repeated if feasible.

Blind PE samples will be analyzed to assess the quality of the metals measurements made in this verification test. If the percent recovery measured for any target metal in the PE sample falls outside the 80-120% range, the instrumentation will be examined and serviced or maintained as needed, and the PE sample and any other samples associated with it will be re-analyzed. If the PE sample results continue to fall outside the acceptable range, the data will be flagged. The PE samples will be provided by the Verification Test Coordinator, and it will be the responsibility of Chester LabNet to analyze them.

C1.2 Technical Systems Audits

The Battelle Quality Manager will perform a technical systems audit (TSA) at least once during this verification test. The purpose of this audit is to ensure that the verification test is being performed in accordance with the AMS Center QMP,[1] this test/QA plan, published reference methods, and any Standard Operating Procedures (SOPs) used by Battelle. In the TSA, the Battelle Quality Manager or a designee may review the reference methods used, compare actual test procedures to those specified or referenced in this plan, and review data acquisition and handling procedures. In the TSA, the Battelle Quality Manager will tour the environmental chamber laboratory and observe the fixed site sampling or human subject chamber testing; inspect documentation of sample CoC; and review PCIS-specific record books. He will also check calibration certifications for test measurement devices. He may also visit the inorganic laboratory where the metals analysis is conducted, to review procedures and adherence to this plan and applicable reference methods or SOP's. A TSA report will be prepared, including a statement of findings and the actions taken to address any adverse findings. The EPA AMS Center Quality Manager will receive a copy of Battelle's TSA report. At EPA's discretion, EPA QA staff may also conduct an independent on-site TSA during the verification

test. The TSA findings will be communicated to technical staff at the time of the audit and documented in a TSA report.

C1.3 Data Quality Audits

The Battelle Quality Manager will audit at least 10% of the verification data acquired in the verification test. The Battelle Quality Manager will trace the data from initial acquisition, through reduction and statistical comparisons, to final reporting. All calculations performed on the data undergoing the audit will be checked.

C1.4 QA/QC Reporting

Each assessment and audit will be documented in accordance with Section 3.3.4 of the AMS Center QMP.[1] The results of the technical systems audit will be submitted to EPA. Assessment reports will include the following:

- Identification of any adverse findings or potential problems
- Response to adverse findings or potential problems
- Recommendations for resolving problems
- Confirmation that solutions have been implemented and are effective
- Citation of any noteworthy practices that may be of use to others.

C2 REPORTS TO MANAGEMENT

The Battelle Quality Manager, during the course of any assessment or audit, will identify to the technical staff performing experimental activities any immediate corrective action that should be taken. If serious quality problems exist, the Battelle Quality Manager will notify the Battelle AMS Center Manager, who has the authority to direct testing staff to stop work. Once the assessment report has been prepared, the Verification Test Coordinator will ensure that a response is provided for each adverse finding or potential problem and will implement any necessary follow-up corrective action(s). The Battelle Quality Manager will ensure that follow-up corrective action(s) has been taken. The test/QA plan and final report are reviewed by EPA

AMS Center QA staff and EPA AMS Center program management staff. Upon final review and approval, both documents will then be posted on the ETV website (www.epa.gov/etv).

SECTION D

DATA VALIDATION AND USABILITY

D1 DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

The key data review requirements for the verification test are stated in Section B10 of this test/QA plan. The QA audits described within Section C of this document, including the audit of data quality, are designed to assure the quality of the data.

D2 VALIDATION AND VERIFICATION METHODS

Section C of this test/QA plan provides a description of the validation safeguards employed for this verification test. Data validation and verification efforts include the collection of QC samples, the analysis of SRMs and PESs, and the performance of TSAs as described in Section C.

D3 RECONCILIATION WITH USER REQUIREMENTS

This test/QA plan and the resulting ETV verification report(s) will be subjected to review by the PCIS vendor, EPA, and expert peer reviewers. These reviews will assure that this test/QA plan and the resulting report(s) meet the needs of potential users and permitters of PCISs. PCIS and reference sampler data collected under conditions where the quality control requirements shown in Table B-1 were met will be presented in the final report without further comment. PCIS and reference sampler data collected under conditions where the quality control requirements shown in Table B-1 were not met will be flagged and a discussion of the possible impact of those failed requirements will be presented in the final report. The final report(s) will be submitted to EPA in Word Perfect and Adobe ".pdf" format and subsequently posted on the ETV website.

SECTION E

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Appendix A

PCIS Questionnaire

PCIS Questionnaire	Strongly Agree	**(please circle one number)**	Strongly Disagree
1. The pump noise was too loud.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
2. The weight of the pump was uncomfortable.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
3. It was easy to wear the sampler clipped to my shirt.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
4. I could talk on the phone easily while wearing the sampler.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
5. I would volunteer to wear this sampler for another 24 hours.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
6. I could not tell if the sampler was operating.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
7. I was always conscious of the sampler.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
8. I had problems putting the sampler back on.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
9. I slept well while the sampler was operating near me.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
10. It was hard to take the sampler off in order to shower.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
11. I was comfortable wearing the pump.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
12. Sometimes I forgot that I was wearing the sampler.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
13. I was not able to wear this sampler for longer than 4 hours.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
14. It was hard to think while wearing the sampler.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
15. I like wearing the sampler.	Strongly Agree	1 2 3 4 5 6	Strongly Disagree
16. I did not wear the sampler for approximately _____ hours during the 24-hr sampling period.			
17. I was able to follow the air sampling instructions that Battelle gave me exactly. Yes No (circle one)			
PCIS Questionnaire **Page 1 of 2**			

PCIS Questionnaire (continued)
18. The sampler drew attention to me so that I had to explain to people what I was doing. Yes No (circle one)
19. I felt comfortable wearing the inlet clipped to my shirt. Yes No (circle one)
20. The sound of the pump sometimes got louder and/or softer. Yes No (circle one)
21. The pump stopped running even though I didn't do anything to it. Yes No (circle one)
22. I accidentally dropped the pump. Yes No (circle one)
23. I slept for approximately _____ hours while the sampler operated near me.
24. I could not sleep with the sampler operating near me. Yes No (circle one)
Please add any comments or suggestions you may have:
PCIS Questionnaire **Page 2 of 2**

Appendix B

Time/Activity Diary

Time/Activity Diary

Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

Activity Number(s): **Do NOT leave blank**	midnight	12:30 am	1 am	1:30 am	2 am	2:30 am	3 am	3:30 am	4 am
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court ☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary
Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

4 am | 4:30 am | 5 am | 5:30 am | 6 am | 6:30 am | 7 am | 7:30 am | 8 am

Activity Number(s): Do NOT leave blank								
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐
Outside 	☐	☐	☐	☐	☐	☐	☐	☐
At Work 	☐	☐	☐	☐	☐	☐	☐	☐
Fill in the name of locations not listed; examples:gym, tennis court	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐

Notes:

Time/Activity Diary

Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

Activity Number(s): **Do NOT leave blank**	8 am		8:30 am		9 am		9:30 am		10 am		10:30 am		11 am		11:30 am		noon
Location: **Inside Home** 	☐		☐		☐		☐		☐		☐		☐		☐		
Outside 	☐		☐		☐		☐		☐		☐		☐		☐		
At Work 	☐		☐		☐		☐		☐		☐		☐		☐		
Fill in the name of locations not listed; examples:gym, tennis court	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
Bath/Shower 	☐		☐		☐		☐		☐		☐		☐		☐		
Pump Not Operating	☐		☐		☐		☐		☐		☐		☐		☐		

Notes:

Time/Activity Diary

Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

Activity Number(s): **Do NOT leave blank**	noon	12:30 pm	1 pm	1:30 pm	2 pm	2:30 pm	3 pm	3:30 pm	4 pm
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

Activity Number(s): **Do NOT leave blank**	4 pm	4:30 pm	5 pm	5:30 pm	6 pm	6:30 pm	7 pm	7:30 pm	8 pm
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 1

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

		8 pm	8:30 pm	9 pm	9:30 pm	10 pm	10:30 pm	11 pm	11:30 pm midnight
Activity Number(s): Do NOT leave blank									
Location:	**Inside Home**	☐	☐	☐	☐	☐	☐	☐	☐
	Outside	☐	☐	☐	☐	☐	☐	☐	☐
	At Work	☐	☐	☐	☐	☐	☐	☐	☐
Fill in the name of locations not listed; examples:gym, tennis court	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	Bath/Shower	☐	☐	☐	☐	☐	☐	☐	☐
	Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐

Notes:

Time/Activity Diary

Day 2

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

Activity Number(s): **Do NOT leave blank**	midnight	12:30 am	1 am	1:30 am	2 am	2:30 am	3 am	3:30 am	4 am
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 2

Activity Number:

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: | | | | | |

Date: | | | | | | |

	4 am		4:30 am		5 am		5:30 am		6 am		6:30 am		7 am		7:30 am		8 am
Activity Number(s): Do NOT leave blank																	
Location: **Inside Home** 	☐		☐		☐		☐		☐		☐		☐		☐		
Outside 	☐		☐		☐		☐		☐		☐		☐		☐		
At Work 	☐		☐		☐		☐		☐		☐		☐		☐		
Fill in the name of locations not listed; examples:gym, tennis court	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
	☐		☐		☐		☐		☐		☐		☐		☐		
Bath/Shower 	☐		☐		☐		☐		☐		☐		☐		☐		
Pump Not Operating	☐		☐		☐		☐		☐		☐		☐		☐		

Notes:

Time/Activity Diary

Day 2

Activity Number: _____

1 = Sleeping

2 = Eating

3 = Sitting

4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

Activity Number(s): **Do NOT leave blank**	8 am	8:30 am	9 am	9:30 am	10 am	10:30 am	11 am	11:30 am	noon
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court ☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 2

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Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

	noon	12:30 pm	1 pm	1:30 pm	2 pm	2:30 pm	3 pm	3:30 pm	4 pm
Activity Number(s): **Do NOT leave blank**									
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court ☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 2

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Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

	4 pm	4:30 pm	5 pm	5:30 pm	6 pm	6:30 pm	7 pm	7:30 pm	8 pm
Activity Number(s): **Do NOT leave blank**									
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court ☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes:

Time/Activity Diary

Day 2

Activity Number: _____

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4 = Moderate Activity (e.g., walking)

5 = Intense Activity (e.g., jogging)

Subject ID: ☐☐☐☐☐

Date: ☐☐ ☐☐ ☐☐

	8 pm	8:30 pm	9 pm	9:30 pm	10 pm	10:30 pm	11 pm	11:30 pm	midnight
Activity Number(s): **Do NOT leave blank**									
Location: **Inside Home** 	☐	☐	☐	☐	☐	☐	☐	☐	
Outside 	☐	☐	☐	☐	☐	☐	☐	☐	
At Work 	☐	☐	☐	☐	☐	☐	☐	☐	
Fill in the name of locations not listed; examples:gym, tennis court ☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	☐	☐	
Bath/Shower 	☐	☐	☐	☐	☐	☐	☐	☐	
Pump Not Operating	☐	☐	☐	☐	☐	☐	☐	☐	

Notes: