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Environmental Technology Verification Quality Assurance Project Plan

General Ventilation Filters

Prepared by

RTI

Research Triangle Institute

Under a Cooperative Agreement with

EPA U.S. Environmental Protection Agency

ETV ETV ETV

Notice

This document has been subjected to the U.S. Environmental Protection Agency's quality assurance and administrative reviews and has been approved for publication.

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ENVIRONMENTAL TECHNOLOGY VERIFICATION QUALITY ASSURANCE PROJECT PLAN

GENERAL VENTILATION FILTERS

Prepared by

Research Triangle Institute
Research Triangle Park, NC

EPA Cooperative Agreement No. CR 822870-01

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A3: Distribution List

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Dr. Leslie E. Sparks

Research Triangle Institute
Dr. David Ensor
Ms. Deborah Franke
Dr. C. E. Tatsch
Ms. J. M. Elion

List of Acronyms/Abbreviations

ANSI	American National Standards Institute
ASHRAE	American Society of Heating, Refrigerating, and Air-conditioning Engineers
ASME	American Society of Mechanical Engineers
CV	correlation of variance
DQO	Data Quality Objective
EPA	Environmental Protection Agency
ETV	Environmental Technology Verification
HEPA	High Efficiency Particulate Air
ISO	International Standards Organization
KCl	potassium chloride
OPC	optical particle counter
PSE	particle size (removal) efficiency
PSL	polystyrene-latex
QA	Quality Assurance
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
RTI	Research Triangle Institute
SOP	standard operating procedure

References

RTI. *Environmental Technology Verification Test Method for General Ventilation Filters,,* Research Triangle Park, NC. 1999.

RTI. *Environmental Technology Verification Test Protocol for General Ventilation Filters,* Research Triangle Park, NC. 1999.

SECTION A: PROJECT MANAGEMENT

A4: Project/Task Organization

The US Environmental Protection Agency (EPA) has overall responsibility for the Environmental Technology Verification (ETV) Program for Indoor Air Products. Under cooperative agreement with EPA, Research Triangle Institute (RTI) will perform the testing, evaluate the data, and prepare the project deliverables, including the verification report and the verification statement. The various quality assurance (QA) and management responsibilities are
divided between EPA and RTI key project personnel as defined below. The lines of authority between key personnel for this project are shown on the project organization chart in Figure 1.

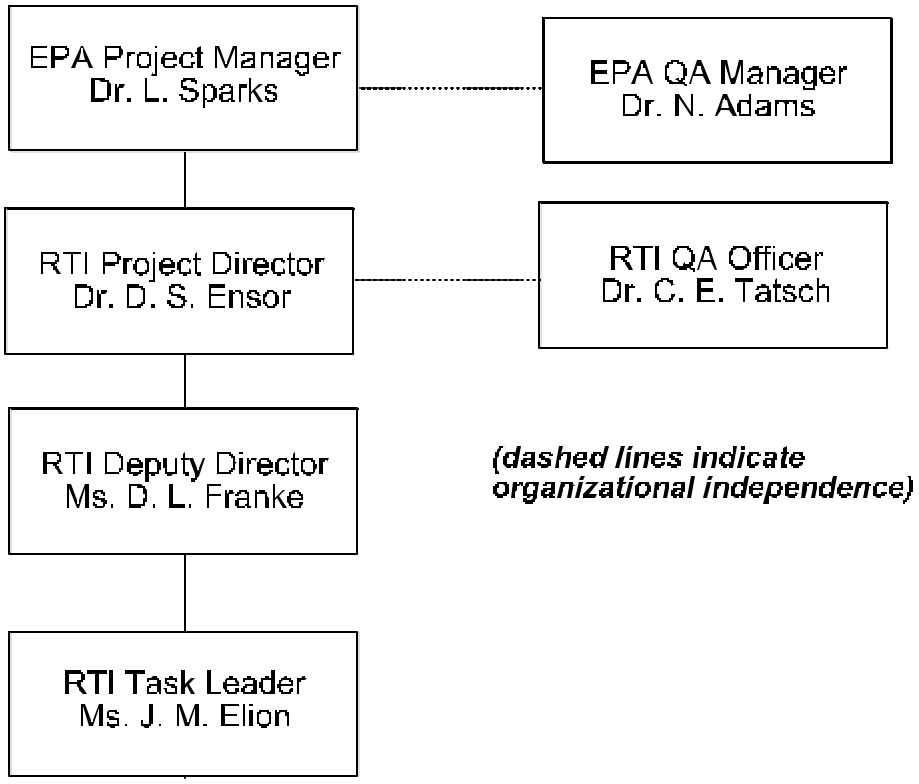

Figure 1. Project Management Organization Chart for
ETV Indoor Air Products Pilot Program General Ventilation Filters

A4.1 Management Responsibilities

Project management responsibilities are divided among the EPA personnel and RTI personnel as listed below.

A4.1.1 EPA Project Manager

The EPA Project Manager, Dr. Les Sparks, has overall responsibility for the program. He is responsible for granting final approval of project plans and reports and seeing that plans are implemented according to schedule, and he has the authority to commit the resources necessary to meet project objectives and requirements.

A4.1.2 RTI Project Manager

The RTI Project Director, Dr. David Ensor, and RTI Deputy Director, Ms. Deborah Franke, are responsible for task implementation and technical quality control. The RTI Program Director is also responsible for the following tasks:

- Monitor and direct the task leaders,
- Prepare quarterly progress reports,
- Update and distribute revisions of the Quality Assurance Project Plan (QAPP) as necessary, and
- Oversee preparation of verification reports and verification statements.

A4.1.3 RTI Task Leader

The RTI Task Leader, Ms. Jenni Elion, is responsible for the following tasks:

- Defining task objectives
- Develop a detailed work plan schedule,
- Review work progress to ensure that task budgets and schedules are met,
- Prepare verification reports and verification statements.

A4.2 Quality Assurance Responsibilities

QA responsibilities are divided among the EPA personnel and RTI personnel as listed below.

A4.2.1 EPA Quality Assurance Officer

The EPA QA Manager, Dr. Nancy Adams, will conduct audits of RTI's QA System and of specific technical activities on the project. She will be available to resolve any QA issues relating to performance to EPA's QA requirements. Specific functions and duties of the EPA QA Manager include approving the contents of this QAPP and subsequent revisions and reviewing QA reports prepared by RTI, including QA evaluations and audits.

A4.2.2 RTI Quality Assurance Officer

The RTI Quality Assurance Officer (QAO), Dr. C. E. Tatsch, is responsible for ensuring that QA/QC procedures described in this QAPP are followed. In addition, the RTI QAO will:

- Maintain regular communication with the EPA QAO regarding QA issues
- Report on the adequacy, status, and effectiveness of the QA program on a regular basis to the Task Manager

- Conduct audits of lab activities as necessary and prepare audit reports.
- Ensure that corrective action, if necessary, is properly implemented and documented.

A5: Background Information

The ETV Test Protocol for General Ventilation Filters is intended to provide data on the particle-size dependent, or fractional, efficiency of general air ventilation filters. The data are intended to be used for several purposes:

- to allow users to compare products
- to encourage development of innovative filter media.

The test duct required for this method operates under positive pressure to minimize infiltration of room aerosol. Aerosol injection is located upstream of a mixing baffle to provide aerosol mixing with the airstream. Aerosol concentration is measured both upstream and downstream of the test section to obtain the challenge and penetrating aerosol concentrations, respectively. The test duct is designed to allow the use of a single set of aerosol instrumentation to perform both the upstream and downstream aerosol concentration measurements with a minimum of particle losses.

A single filter is subject to a series of tests: resistance vs. airflow of the clean filter at various airflow rates, particle size removal efficiency (PSE) of the clean device, and PSE of the filter when incrementally loaded with synthetic dust.

A6: Task Description

The task consists of three steps. The first step is to identify and acquire general ventilation filters qualified for verification under the ETV Test Protocol for General Ventilation Filters. The next step is to actually perform the testing on various ventilation filters. The final step is to complete the verification report and verification statement and submit them to the EPA.

A7: Data Quality Objectives and Criteria for Measurement Data

Data Quality Objectives (DQOs) are qualitative and quantitative statements designed to ensure that the type, quality, and quantity of data used are appropriate for the intended application. The DQOs for the ETV Indoor Air Quality Pilot Program are ETV program goals are:

- To verify the environmental performance characteristics of commercial-ready technology through the evaluation of objective and quality assured data; and
- To provide potential purchases and permitters with an independent and credible assessment of what they are buying and permitting.

A successful test will be defined as a test where

- the test rig itself meets the systems qualification requirements listed in Table 2 of the ETV Test Method for General Ventilation Filters , Section 6.

- the measured parameters fall within the quality control limits listed in Table 3 of the ETV Test Method for General Ventilation Filters.

Comparability is more important than the actual values; therefore, data generated from a successful test will be acceptable for meeting the DQOs.

The critical measurements consist of upstream and downstream particle counts used to compute penetration, volumetric flowrate through the filter, and the pressure drop across the filter.

A7.1 Penetration

There are presently no standards available to directly "calibrate" the test system for penetration. However, a number of parameters can be checked to verify proper performance. 0% and 100% penetration measurements are made by using a HEPA filter and an empty test section, respectively. Checks are performed on the optical particle counter (OPC) zero-count by sampling HEPA-filtered air and of its sizing accuracy by sampling known size monodisperse PSL spheres. Operational checks are made during the test to ensure that the particle concentration does not exceed the capability of the OPC while at the same time having sufficient concentration to provide adequate particle counts upstream of the filter to provide a meaningful test.

A7.2 Volumetric Flow Rate

Flow rate is measured via the pressure drop across an ASME long radius flow nozzle mounted in the duct downstream of the filter. It is the primary standard for the laboratory. Prior to use, the nozzle is visually inspected to be free from defects. The installation of the nozzle in the duct will be inspected to confirm that it is seated in place.

A7.3 Pressure Drop Across the Filter

The pressure drop across the filter will be measured with an inclined manometer. The zero and level of the manometer will be confirmed and connecting tubing inspected for integrity.

A7.4 Ancillary Measurements

In addition to the critical measurements of Table 3 in the ETV Test Method for General Ventilation Filters, measurements of the in-duct temperature and relative humidity, and room atmospheric pressure will be made. These measurements are not critical to the program and are being collected simply to document the general test environment. A wet and dry bulb psychrometer will be used for determination of temperature and relative humidity and a mercury barometer (located in an adjoining lab) for atmospheric pressure. No specific quality control checks on these instruments are planned other than an inspection of the instruments for mechanical faults (e.g., mercury separation in the thermometers, poor tubing connections), and inspection of the data for reasonableness.

A7.5 Representativeness

In the context of this ETV general ventilation filter verification program, and given that the test conditions are set by the ETV Test Method for General Ventilation Filters, representativeness is an issue of which filters are selected for testing and how are they selected to ensure that the samples tested are representative (or, at least, not "hand picked" in a way that might bias the results).

The selection of the test ventilation filters will be governed by the ETV Test Protocol for General Ventilation Filters.

A7.6 Comparability

All tests will be performed following the same test data collection techniques, measurement procedures, and methods. Therefore, all the results will be comparable.

A8: Special Training Requirements/Certification

The ETV program is open to multiple test lab participation. In addition to RTI, it is anticipated that from one to three other laboratories will be available for testing. All participating labs must accept on-site audits by EPA and/or RTI personnel. The audit will include running an efficiency test on a reference filter provided by EPA.

To participate in ETV testing, labs must:

- Possess the equipment and facilities required to perform these tests, as specified in ETV Test Method for General Ventilation Filters in-house lab).
- Be registered as ISO 9000 compliant or meet ANSI E4 specification and guidelines for Quality Systems for Environmental Data collection and Environmental Technology Programs.
- Allow on-site audit by EPA and/or their representatives.
- Prepare a Quality Assurance Project Plan (QAPP).

The method chosen for analysis of particle size efficiency of ventilation filters in the laboratory (ETV Test Method for General Ventilation Filters) is restricted to use by, or under the supervision of, personnel experienced in the use of an OPC and skilled in the interpretation of raw count data. Each person must demonstrate his or her ability to generate acceptable results with this method.

A9: Documentation and Records

This section identifies the documents and reports to be generated as part of the verification program and the information to be included in the verification reports and verification statements. A description of the data management system established for this task is presented in Section B10.

A9.1 Laboratory Documentation

Documentation requirements are specified in the ETV Test Method for General Ventilation Filters, Section 11.

A9.2 QA Reports

As described in Section C1, EPA personnel or designated representatives may audit the test laboratory at the discretion of EPA. The auditors will prepare an audit report summarizing the observations and findings of those audits. As needed, the audit reports will be supplemented by a Corrective Action Request to document changes required to meet established quality objectives.

A9.3 Reporting

The report will consist of calculated and reported data as specified in ETV Test Method for General Ventilation Filters, Section 11. Raw data shall be included as an appendix.

SECTION B: SAMPLING PROCESS DESIGN

B1: Sampling Process Design

The procedure uses laboratory-generated potassium chloride particles dispersed into the airstream as the test aerosol. A particle counter(s) measures and counts the particles in twelve size ranges both upstream and downstream for the efficiency determinations. The procedure also describes a method of loading the filter with synthetic dust to simulate actual use conditions. A composite curve representing the minimum performance in each size range is developed from the performance curves for the initial "clean" filter and under dust loading conditions.

B2: Sampling Methods Requirements

Sampling method requirements and critical dimensions and configurations of the test apparatus are specified in ETV Test Method for General Ventilation Filters, Section 5.

B3: Sample Handling and Custody Requirements

Upon receipt of the test filters, the ventilation filters will be serially numbered with a permanent marker (or other means as appropriate). All filters for this study will be stored in a single common area, separate from all other similar devices.

B4: Analytical Methods Requirements

The analytical methods selected are described in ETV Test Method for General Ventilation Filters.

B5: Quality Control Requirements

The apparatus will be tested to verify that the test rig and sampling procedures are capable of providing quantitative reliable particle size efficiency measurements. The qualification tests and procedures are detailed in ETV Test Method for General Ventilation Filters, Section 6. The system qualification requirements are specified in ETV Test Method for General Ventilation Filters, Table 1.

B6: Instrument/Equipment Testing, Inspection, and Maintenance Requirements

Qualification tests will be conducted as part of each test run, monthly, biannually, or after a change that may alter performance, depending on the schedule provided in Table 3 of the ETV Test Method for General Ventilation Filters.

B7: Instrument Calibration and Frequency

Calibration will be performed in accordance with manufacturer's recommendations; at the least, calibrations will be performed annually.

B8: Inspection/Acceptance Requirements for Supplies and Consumables

The loading dust is a blend of test dust, powdered carbon, and cotton linters. It shall conform to

requirements specified in ETV Test Method for General Ventilation Filters, Section 5.7.

B9: Data Acquisition Requirements (Non-direct measurements)

No types of data are needed for project implementation or decision making that would be obtained from non-measurement sources such as computer databases, programs, literature files, or historical databases.

B10: Data Management

This section identifies the activities and processes planned for documenting the traceability of the conclusions and information in the verification report.

B10.1 Data Recording

Data for this task will be collected by computer and by handwritten entries. Observations and records such as sample description and collection information will be recorded manually in lab notebooks kept exclusively for this task. Output data generated by the OPC instruments will be fed directly into a computer file and stored as a spreadsheet; printed output will be taped into the lab notebook.

B10.2 Data Quality Assurance Checks

QA checks of data as early as possible are essential to provide early warning of potential problems. Several levels of QA checks are specified in ETV Test Method for General Ventilation Filters, Section 7.

B10.3 Data Analysis

Data analysis will be performed using commercially available software capable of reading the raw data from a spreadsheet and calculating a series of equations.

B10.4 Data Storage and Retrieval

Laboratory notebooks containing manually recorded information and data output generated from instrumentation will be stored in the custody of the Task Leader for the duration of the project.

Spreadsheet files including raw and calculated data will be stored on computers. The files will be downloaded to a network server backed up nightly on magnetic tape.

Following policy at RTI, project files will be archived offsite at a secure facility for a minimum of five years following delivery of the verification report. The records will not be destroyed without written approval from EPA.

SECTION C: ASSESSMENT/OVERSIGHT

C1: Assessments and Response Actions

C1.1: Audits

Test labs will be subject to both external and internal audits. The external audit will be conducted by EPA or a designated representative before testing begins to verify that the laboratory meets the qualifications set forth in Section A8 and that the system qualification tests meet the limits set forth in Table 1 of the ETV Test Method for General Ventilation Filters. At a minimum, a second external audit will be conducted to verify that the laboratory is following the test procedure. The auditor(s) will document their findings and note where corrective actions are necessary. The auditor(s) will distribute audit reports to those listed in Section A3, and the supervisor whose lab was audited.

C1.2: Corrective Actions

Technical personnel working on each task will have the direct responsibility for ensuring that the QA plan is implemented, that the operating parameters are within acceptable limits, and that corrective actions are taken when appropriate. Corrective action will be taken whenever measurement accuracy or bias is outside the limits of objectives for the critical measurements. Corrective actions include:

- problem identification;
- attempting to find the cause;
- attempting immediate repairs (if possible);
- reporting or documenting the problem;
- planning for corrective action (if major repairs are needed);
- checking that problem was corrected;
- documenting the corrective actions taken; and
- recommending changes to instruments, Standard Operating Procedures (SOPs), etc. to avoid similar future occurrences.

The QAO and the Task Leader will be jointly responsible for proper documentation of Corrective Actions. Minor corrective actions are to be recorded in the laboratory notebooks. Major problems will be addressed as outlined above. All corrective actions will be noted in the test report. Depending on the time and expense involved with necessary corrective actions, it will be necessary to consult the Program Manager or the sponsor before implementing any changes in the planned activities.

C2: Reports to Management

Audit reports will be sent to all those on the distribution list for the QAPP. Audit reports will be included as appendices to the verification report.

The Task Manager will prepare monthly status reports for the RTI Program Manager and RTI Quality Assurance Manager.

SECTION D: DATA VALIDATION AND USABILITY

D1: Data Review, Validation, and Verification Requirements

The test is acceptable if all the measured parameters fall within the limits prescribed in Table 3 of the ETV Test Method for General Ventilation Filters, Section 7.

The calculations required to determine particle size efficiency of the filter are presented in ETV Test Method for General Ventilation Filters, Section 10.

The test operator is responsible for checking that all measured parameters fall within prescribed limits before continuing testing.

D2: Validation and Verification Methods

Each verification report will be reviewed by the RTI QAO for compliance with the applicable method and for the quality of the data reported.

The RTI QAO will check for the following:

- Data completeness
- Blanks
- Initial and continuing calibrations
- QC reference and internal standards

D3: Reconciliation with User Requirements

Each ETV verification statement will summarize testing conditions and will state test results. Each ETV test report will present all critical and ancillary (e.g., temperature and humidity) measurements.

The data quality objectives are penetration, volumetric flowrate through the filter, and the pressure drop across the filter. If the critical measurements discussed in Section A7 do not meet the criteria described in Table 3 of the ETV Test Method for General Ventilation Filters, test results will not be considered valid and tests will be repeated after appropriate corrective actions are taken. Data not meeting minimum criteria will not be used in filter evaluation.