Quality Management Plan

EPA Clean Air Research Center

Southeastern Center for Air Pollution and Epidemiology

Emory University and Georgia Institute of Technology

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Management Approvals:

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Co-Director — Date

Armistead (Ted) Russell — 3/16/11
Co-Director — Date

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Quality Assurance Manager — Date

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This Quality Management Plan (QMP) provides a summary of the specific quality management (QM) activities that will be implemented within this Center and describes our approach for establishing and maintaining the highest standards of conducting research. QM practices will be comprehensive and related to statistical, ethical, and practical elements of study design, measurement techniques, data collection and recording, and data analysis. A quality assurance and control (QA/QC) system for the proposed Center will also be developed under this program that meets or exceeds data quality objectives of the United States Environmental Protection Agency (USEPA). Throughout the study, emphasis will be placed on the technical accuracy of the work done. QM relies most on the selection and proper implementation of the most efficient research techniques, careful and honest recording of measurements, and objective assessment of potential measurement and modeling errors and their likely impacts. Towards this end, we have designated a QA Manager and individuals to serve as Center QA Advisors with extensive experience implementing rigorous QA protocols and ensuring that the quality control responsibilities are being met by each project director. Although the QA Advisors can help integrate and oversee these functions, each project's principal investigator (PI) and individual researchers will ultimately be committed to the implementation of our QA protocols to achieve high standards for data quality.

1) Management and Organization

The Southeastern Center for Air Pollution and Epidemiology (SCAPE) is a multi-institutional, multi-disciplinary Center designed to address critical issues relating to the public health impacts of ambient air pollution. The overarching theme of the Center is a focus on characterizing ambient air pollution *mixtures* and elucidating their role in human health risks associated with air pollution. Novel measurements and modeling approaches will be applied in the context of a tiered multi-scale assessment of the health risks of mixtures characterized based on: 1) biological considerations (oxidants); 2) environmental management (sources); 3) evidence-based considerations (traffic emissions); 4) empirical assessment (data-based approach).

Four research projects will be supported by three cores: an Administrative Core, an Air Quality Core and a Biostatistics Core. Project 1 will develop and deploy instrumentation to measure oxidants (including aerosol reactive oxygen species) and other species of interest to better understand their origins and atmospheric transformation and for use in characterizing mixtures for the three health studies. Project 2 will make direct use of these measurements to confirm associations with markers of oxidative stress in commuters. Projects 3 and 4 will use a combination of measurements and modeled air quality estimates in large population studies, with Project 3 investigating questions regarding risks of *in utero* and early life exposures to air pollutant mixtures in two major new birth cohorts and Project 4 assessing underlying consistencies in morbidity associations across selected cities that have comprehensive daily air

pollution characterization. The health projects include assessment of potentially sensitive and vulnerable subpopulations.

The Center is led by Drs. Paige Tolbert and Armistead (Ted) Russell, Co-Directors (Dual PIs of Center application); they will also serve these roles for the Administrative Core. This leadership team will be the ultimate decision-making unit of the Center on scientific, administrative and fiscal issues. Programmatic decisions will be made in conference with the Executive Committee, and, as appropriate, with input from the External Advisory Panel, described below. In addition to overall oversight of the entire Center, Dr. Tolbert will manage the health studies (largely based at Emory University), while Dr. Russell will manage the air quality work (largely based at Georgia Tech).

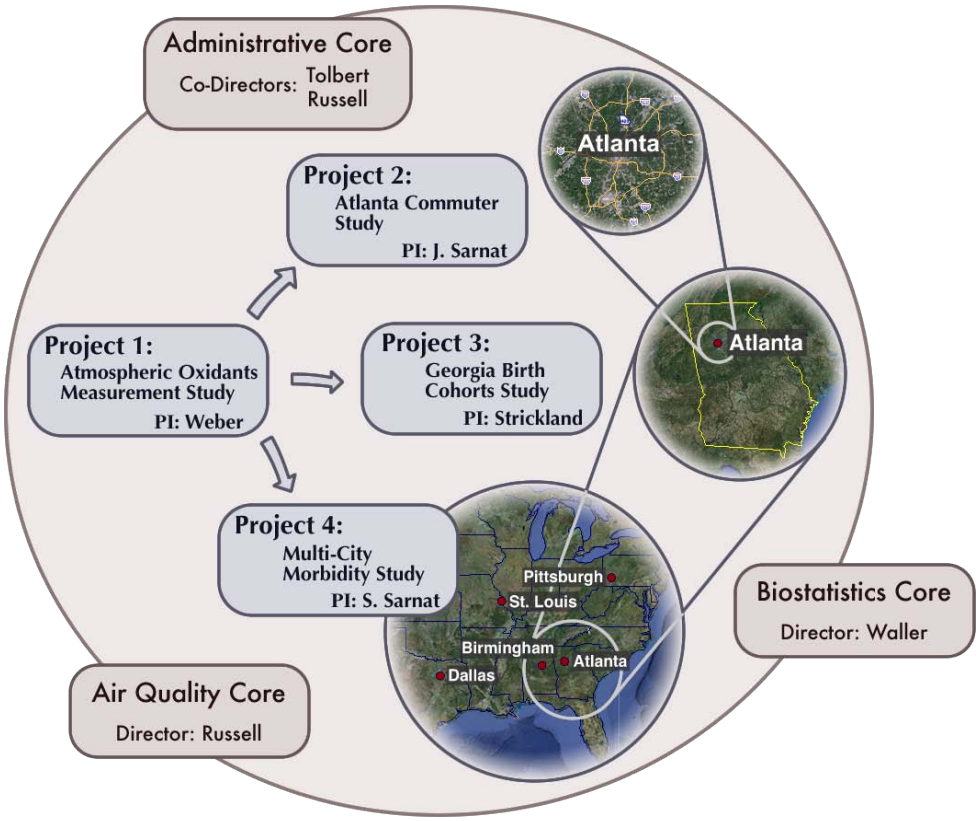

Figure 1: Center Structure

QA Manager

The QA Manager, Kate Hodgins, will serve as a liaison between the air quality and health studies, actively monitoring progress and facilitating flow of communication. She will be responsible for maintaining the Center website and will assist the Center Co-Directors in preparation of reports on Center activities to be submitted by the Co-Directors to the USEPA. Ms. Hodgins will also serve as the QA Manager for the Center, responsible for ensuring that the QM Program is carried out as planned, with input from the two QA Advisors, described below. The QA Manager will not be involved in any data collection or use activities. Ms. Hodgins holds a JD and an MPH in global environmental health. Ms. Hodgins worked with a large air pollution data set for her master's thesis and thereby gained experience in research quality issues relevant to the Center projects.

Quality Assurance Advisors

Two QA Advisors have been designated to administer the QM program which includes the development and implementation of the QA/QC plan. Dr. Mitch Klein (Emory), a member of the Biostatistics Core, has been designated to serve as the QA Advisor responsible for QA practices pertaining to all health outcome data used in Projects 2, 3, and 4. Dr. Guangxuan Zhu (Georgia Tech), a member of the Air Quality Core, has been designated as a second QA Advisor who will be responsible for QA practices pertaining to all air pollution data used in Center projects. Both Officers will assist all projects and cores, working with each of the individuals responsible for QA/QC on the projects and cores, helping design the QA/QC protocols (e.g., QAPPs, SOPs), developing audit forms, and verifying that the protocols are adhered to and any problems are rectified. QA Advisors will also work with the QA Manager in the Administrative Core to coordinate QA/QC activities and report directly to the Center Co-Directors.

Quality Control Reviewers

Each PI will be responsible for designating a Quality Control (QC) Reviewer in their QAPP to assess air quality and health data.

Subcontracting of QA Responsibilities

The QA Manager and Advisors will be employed by Emory and Georgia Tech. Should the Center Director deem it to be in the best interest of the Center to subcontract a QA position, EPA will be notified for permission. QA responsibilities are assigned to each PI as previously noted; some of project investigators may be affiliated with institutions other than Emory University and will therefore be sub-awardees or contractors.

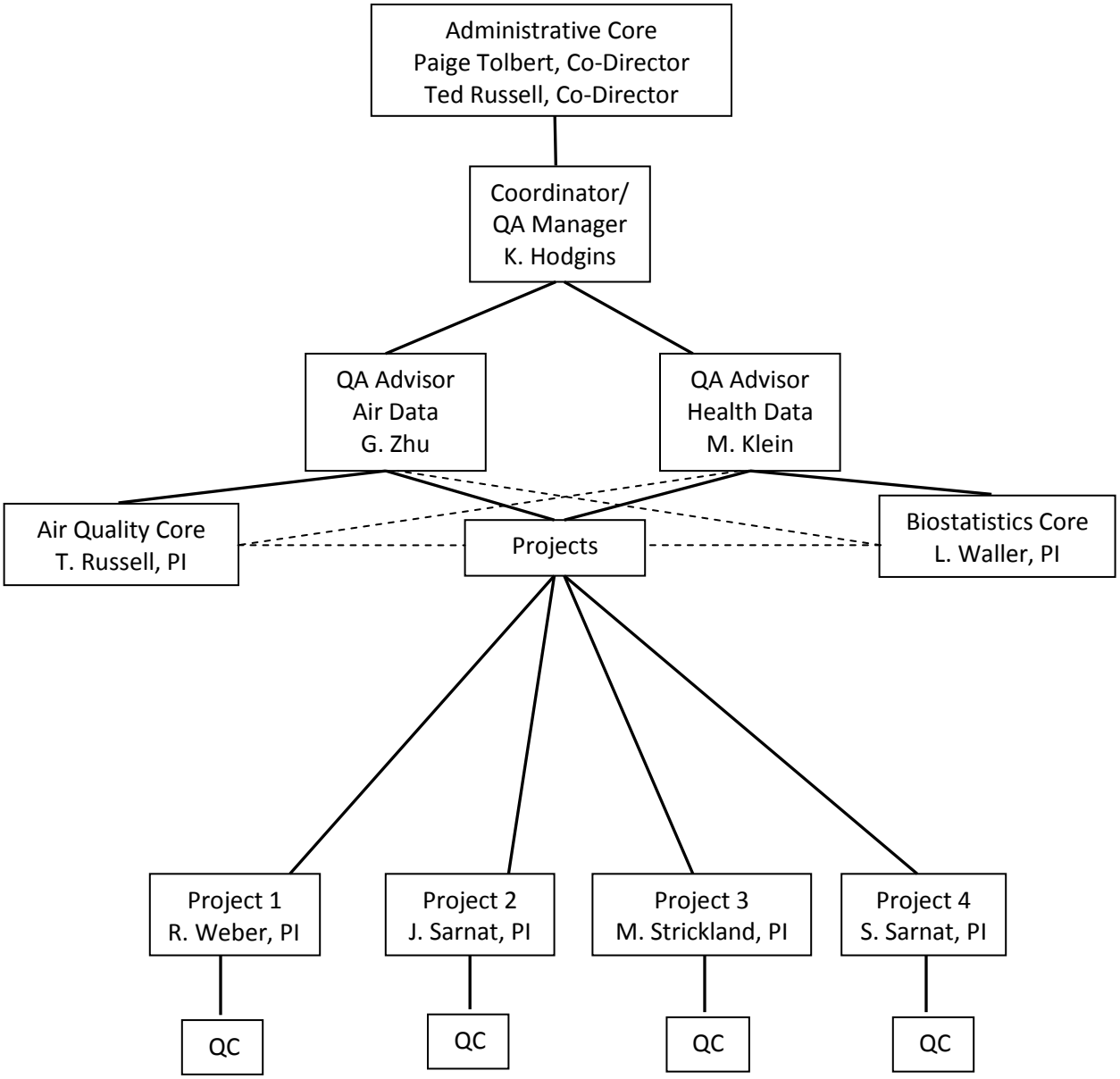

Figure 2: Quality Management Organizational Chart

Management Communication Plan

Frequent formal and informal communication is essential for management of any large research effort. Center Co-Directors will be the ultimate decision-making unit of the Center. The location of the Co-Directors at the two primary research institutions involved in the Center activities will facilitate regular interactions among managers at various levels at both institutions.

Programmatic decisions will be made in conference with the Executive Committee, and with input from the External Advisory Panel, as appropriate. The Executive Committee will be comprised of the Center Co-Directors, the PIs and Core Leaders, and will convene monthly. An External Advisory Panel will be formed to provide independent technical input to the Center investigators and to assess the scientific quality and progress of the projects. The panel will evaluate the merit and contribution of existing and future research projects, and the relevance and importance of individual research elements to accomplishing overall goals of the Center. The panel will be composed of twelve individuals, one of whom will take on the role of chair, and the others assigned lead responsibility for one or two projects or cores. The panel member assigned to a given project will monitor progress of that project, gather input from the entire panel and provide collective feedback to the PI (through the panel chair). An annual meeting with the advisory panel will be convened by the Administrative Core, at which formal presentations will be made on each project and core followed by open discussion. A Research Review Committee will be assembled for the purpose of 1) identifying promising new directions for the research program that could be incorporated into existing projects, and 2) soliciting and reviewing mini-proposals for new work to be internally funded by the Center.

2) Quality System Components

The Quality System is composed of Center-wide and project-specific quality documentation, reviews and assessments. Table 1 details the frequency of program or system audits, associated quality documents and the individual(s) responsible for drafting, updating, and implementing documentation, as well as the individual(s) responsible for program evaluations.

Table 1: Program Evaluations

Program	Documentation	Program Manager(s)	Evaluation	Evaluator
Quality Management	QMP	QA Manager	Initial approval and annually	Center Co-Directors
Quality Assurance	QAPPs and SOPs	PIs QA Advisors	1) QAPP: Initial approval and annually 2) TSAs	1) Co-Directors, QA Manager, QA Officers, PI 2) QA Manager
Data Quality	QAPP: Data Quality Objectives	QC Reviewer	QAPP-specified Data Quality Assessments	PIs
Human Subjects Protection	IRB and HIPAA	PIs	Initial approval and annually	QA Manager
Data Management	Data Management Plan	QA Advisors	Initial Approval and Annually	QA Manager

Dedication to continued improvement is critical to the success of the Quality System components. To accomplish this, the QM program must provide a structure to allow for assessment of all program activities and to require appropriate response to assessment findings. Brief descriptions of Quality System documentation and the process for assessment and response are described below.

Quality Management

The Center Co-Directors will review the QMP annually to reconfirm the suitability and effectiveness of the approved QM practices. The QA Manager will work with the Center Co-Directors to remedy any deficiencies and submit a report of such changes to USEPA. If significant changes are made to the QMP that affect the performance of work for USEPA, the entire QMP will be re-submitted. Any changes in QA policy and procedures that occur between annual reviews will be documented in a timely fashion.

Quality Assurance

Each research project will develop and implement a Quality Assurance Project Plan (QAPP) that meets or exceeds "EPA Requirements for Quality Assurance Project Plans" (EPA QA/R-5). No work with environmental data will begin until the QAPP has been written and reviewed and approved for completeness and compliance with the R-5 document.

Each QAPP will be drafted by the PIs and submitted to the QA Advisors, QA Manager, and Center Co-Directors for review based on a modified version of the NCER QAPP checklist developed during the QAPP development process. Documentation of approval will be indicated by a completed signature cover page for the QAPP, including signatures of the PI, QA Advisors, QA Manager, and Center Co-Directors. Signed copies of the QAPPs will be kept on file with the QA Manager.

Project PIs are responsible for ensuring that the QAPP is distributed and reviewed by all individuals involved in their project research, including individuals from institutions outside of Emory and Georgia Tech. The two QA Advisors and each PI will be jointly responsible for annual reviews of project methods and QA procedures. The QA Advisors will inform the QA Manager of any deficiencies in data quality or QA/QC procedures, and will work with the project's PI to develop a plan to remedy deficiencies as soon as possible. Any changes in data collection techniques or QA/QC procedures that occur between annual reviews will be reported to the QA Advisors immediately.

The QA Manager will conduct Technical Systems Assessments (TSAs) to qualitatively document the degree to which the procedures and processes specified in the QAPPs are being followed. TSAs will be conducted on-site for each project during the first year research is being performed and once every-other year thereafter. On the years in between on-site TSAs, the QA Manager will review the checklist by conference call or in person. Performance criteria for the TSA will be described in the QAPPs, and the audit checklist will be developed during the QAPP approval process. TSA reports and completed checklists will be maintained by the QA Manager as part of the Center's records.

Project PIs will document operations that require standard procedures for uniformity in their QAPP, as well as the process for preparing, reviewing, approving, revising, and withdrawing these procedures. Proper implementation of and compliance with standard procedures for uniformity will be addressed in the annual assessments conducted by the QA Manager and QA Advisors.

Data Quality

Data quality analysis procedures will be established to assess the air quality and health data. All data generated for internal and external use will meet specific requirements, referred to as

Data Quality Objectives (DQO), for completeness, representativeness, accuracy, precision, and compatibility. Project PIs will be responsible for using the DQO process for each QAPP to determine the appropriate QM practices.

Each PI will designate a QC Reviewer for their project, who will be responsible for documenting and keeping records of QA/QC procedures and any deficiencies that occur. The QC Reviewers are also responsible for periodic Data Quality Assessments (DQAs) to examine the data after they have been collected and verified by project personnel and determine how well the measurement system performed with respect to QAPP performance goals and whether the data were accumulated, transferred, reduced, calculated, summarized, and reported correctly. Audit forms detailing the scope of the review, evaluation criteria, and required corrective action if criteria are not met will be developed during the QAPP review process. The QA Manager will hold completed audit report forms as part of the Center's records.

Human Subjects Protection

Institutional Research Board (IRB) approval or exemption will be obtained for each of the four projects initially, and annual renewals will be obtained as required. All investigators are responsible for maintaining current IRB training requirements throughout the project. The QA Manager will keep all IRB protocols, correspondence and approvals on file, and monitor when IRB renewals are due for each project.

Data Management

Data management is an integral part of this Center proposal due to the reliance on a number of large databases and the need to integrate exposure and outcome databases across multiple projects and work sites. Data management plans, including collection, back-up, collation, transfer, and storage, will be developed and based in the Biostatistics and Air Quality Cores.

3) Qualifications and Training

Project/core directors are ultimately responsible for ensuring that staff members receive appropriate training. Plans for ensuring and documenting that personnel have necessary quality-related qualifications and training, will be included in each QAPP. At a minimum, the PI for each project will report hiring of additional personnel and related training procedures to the QA Manager on a semiannual basis.

In order to maintain and develop personnel capabilities for ensuring superior QM practices, Center project staff will undergo continuing training. Individual researchers requiring access to personal health information protected by HIPAA will be fully trained in HIPAA regulations and human subjects research ethics prior to viewing any such data. All non-investigator staff will be trained by a more experienced administrator or researcher with an appropriate background.

Special emphasis will be given to ethical conduct and other QA issues. The Center will also provide a work environment based on the integrity and professionalism of its staff. Such an environment will help ensure that the work is performed with a dedication to excellence and continuous improvement.

4) Procurement of Items and Services

It is the responsibility of the PIs to ensure that all extramural agreements and responses to solicitations satisfy the project's QAPP-specified technical and quality requirements. Extramural agreements should ultimately be approved by the Center Co-Directors. Additionally, PIs are responsible for ensuring that Suppliers' products will fulfill their intended needs and conform to EPA funding requirements.

5) Documents and Records

All records generated by SCAPE investigators and technical personnel pertaining to SCAPE matters will be maintained as SCAPE records in original paper and/or electronic media. Electronic records and documentation will be stored centrally at Emory University and Georgia Tech, and original paper records and documentation will be stored by the QA Manager at Emory. Document versions will be controlled by including the title, date and version number in the header of each draft. Records and documentation distribution will be made as determined by the QA Manger in consultation with the PIs and Center Co-Directors. Distribution information will be maintained by the QA Manager.

Data for all projects will be stored centrally at Emory University and at Georgia Tech under the auspices of the Biostatistics Core and the Air Quality Core on password restricted servers. Some electronic media will be available for Internet download through the public SCAPE website and a private data exchange system under development for Emory and Georgia Tech SCAPE researchers. Others will be available upon request to the QA Manager. Requests for documents from sources outside the SCAPE community will be addressed to the appropriate PI and/or Center Co-Directors.

We anticipate disseminating our research findings at scientific meetings and publishing manuscripts in the open scientific literature. We will also make an active effort to share our findings with other federal and state agencies charged with environmental health protection, as well as to networks of air quality and health modelers.

6) Computer Hardware and Software

Project PIs will document the use of computer hardware and software in their QAPP. Each PI is responsible for monitoring software licenses and upgrading computer hardware. In the

event that noncommercial software is used for research, the PIs are responsible for submitting a validation report to the appropriate QA Advisor for review and approval.

7) Planning

The unifying theme of the proposed Center's research program is the focus on characterizing ambient air pollution *mixtures* and elucidating their role in human health risks associated with air pollution.

We will approach this overall theme from a number of angles:

First, from a *biologically-based perspective*, we will assess the role of reactive oxygen species (ROS) and other oxidants as a group with potential biological activity relevant to oxidative stress-mediated responses.

Second, from an *environmental management perspective*, we will use a variety of state-of-the-art methods of source apportionment to better understand roles of groups of agents co-emitted from specific sources and their transformation products, helpful for targeting regulatory actions and control strategies.

Third, from an *evidence-based perspective*, we will focus on vehicular emissions and near-roadway impacts, as accumulating evidence supports a major role for traffic in a number of health outcomes, and will directly assess these exposures in a panel setting, as well as developing and using near-roadway impact models in a birth cohort design.

Finally, from an *empirical perspective*, we will use a number of data-based approaches to sort species and group them according to their associations with health endpoints of interest.

The Center will capitalize on the availability of an extremely rich record of speciated, multiphase pollution measurements for the study areas of interest, and will augment this with novel measurement and modeling methods that will be developed and applied in the proposed research. The tiered assessment will be on multiple spatial scales, from the in-vehicle micro-environment to a state-wide assessment to a multi-city assessment across a broad swath of the Southeast and neighboring areas. Finally, the proposed research program will shed light on subpopulations that are particularly susceptible or vulnerable to the effects of ambient air pollution.

Data management is an integral part of this Center. Based on our past projects of similar magnitude, we expect that approximately six terabytes of computer output will be generated in conducting this project, making data management and dissemination planning integral to both the successful conduct of the project, as well as ensuring its legacy and use by others. A Data

Management Plan, including collection, back-up, collation, transfer, and storage, will be based in the Biostatistics and Air Quality Cores.

The Air Quality Core will make use of the output from Project 1, as well as other available air quality data and model output, to develop a Mixtures Characterization Toolkit for use by the three health studies, drawing efficiently on the pooled expertise of the personnel on this core. The Biostatistics Core will provide guidance and support to the health projects in the development and application of modeling approaches that make appropriate use of the mixtures characterizations provided by the Air Quality Core.

Data analysis methods will be determined by PIs in consultation with Biostatistics Core members who are trained and experienced in the development and application of modern statistical methods, and uncertainty/sensitivity analyses will be conducted to determine the influence of model selection and parameterization on key results. Finally, all methods and results will be published in peer review journals, and data will be shared publically when allowable, serving as additional QA/QC activities.

QA/QC needs for health data (Projects 2, 3, 4).

The health data used in the proposed study will include biomarkers of acute cardiorespiratory response (Project 2); historic records of multi-city data on emergency department (ED) visits (Projects 3, 4), hospital admissions (HA) (Projects 3, 4); statewide birth outcomes records (Project 3), Atlanta-area Kaiser Permanente medical records for a pediatric cohort (Project 3). We will apply rigorous qualitative and quantitative measures of quality assessment for these data. For the qualitative assessment of the health outcomes data, we rely on the judgment of the individual hospital data managers and central health data repositories regarding its limitations based on data entry procedures, storage restrictions in the source system, accuracy and reliability of the information in each data field, and any peculiarities in the data resulting from the method of data extraction from the source system.

We will also apply rigorous quantitative measures of quality assessment for the medical record-based health data as has been used for our previous analyses. Univariate statistics and Spearman correlations will be computed and compared between the data sources for each group. The daily counts for all ED visits and case groups of interest will be evaluated for unusual day-to-day variability using frequency tables and univariate statistics. Frequencies of primary diagnosis codes are assessed to evaluate consistency between similar types of hospitals and over time within a single hospital. Systematic differences, for example, in ED visit counts between the HA and in-house data will be examined in detail, which may involve referring back to each individual-level dataset. The daily counts for all ED and HA visits and case groups of interest are evaluated for unusual day-to-day variability using frequency tables and univariate statistics.

QA/QC needs for pollutant data (Projects 1, 2, 3, 4).

Air Quality Core investigators have extensive QA/QC experience, along with the QA Advisor. These investigators follow ANSI/ASQC E4 guidelines and have maintained highly detailed quality assurance plans as part of their previous participation in EPA-funded projects including: the Atlanta Supersite Experiment; Assessment of Environmental Pollution and Community Health in Northwest Florida; Southeastern Center for Integrated Study of Secondary Air Pollutants; and Emissions Inventory and Process Reconciliation Using Molecular Markers and Hybrid/Inverse Photochemical Modeling with Direct Sensitivity Analysis. QA procedures for air quality projects will be based on those used in these previous studies, and include assessment of accuracy, bias, precision, detection limits, completeness, comparability, and representativeness. Particular issues to be addressed for the air quality projects include the use of CALINE and CMAQ air quality modeling systems. Although these models are extensively used and have been peer reviewed, we will conduct additional model evaluations as part of the Center QA/QC activities, relying on data drawn from separate high quality sources (e.g., US EPA AQS; EPA Supersite results; NARSTO database). Air quality model inputs (e.g., from emissions and meteorological models) will be separately evaluated.

Separate procedures will be used to conduct quality assurance for the exposure assessment and receptor modeling portions of the study. A large set of statistical measures are used to assess the quality of the chemical mass balance modeling, and laboratory QA/QC procedures such as traceable standards, multiple instrument calibrations per day, testing of flow rates and losses in the field, field blanks and inter-laboratory comparison are well developed and may be implemented in our study.

For our existing and any newly developed instruments (Projects 1 and 2), the quantitative accuracy of the measurements will be assessed through redundant laboratory and ambient aerosol measurements. All instruments will be frequently checked for background interferences, and compared to standards, in cases where they exist, or through comparisons with other techniques when standards are not yet established. Calibration procedures will be established based on standard operating procedures (SOPs) for the various instruments, including NIST traceable standards where applicable. The criteria of the new air quality samples will include assessment of accuracy, bias, precision, detection limits, completeness, comparability, and representativeness. Field activities to assess data quality for the new measurements will include scheduled sampler collocations, flow checks, routine instrument calibrations and maintenance. For all laboratory analyses, a central aspect of the acceptability criteria for the data will be an accurate reporting of the uncertainty of all reported measurements.

QA/QC procedures will include common data formatting standards for all projects in order to facilitate data sharing within the Center and, where allowable, with the general public. Standard

measurement units, date and time formats, missing data codes, and meta-data formats will be specified and used throughout all Center activities.