Development of Quality Control Parameters and Electronic Data Recording for an Ambient Air Particle Inhalation Exposure System

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Research and Development at EPA

- 1,950 employees
- $700 million budget
- $100 million extramural research grant program
- 13 lab or research facilities across the U.S.
- Credible, relevant and timely research results and technical support that inform EPA policy decisions
National Health and Environmental Effects Research Laboratory

- NHEERL is EPA’s focal point for scientific research on the effects of contaminants and environmental stressors on human health and ecosystem integrity.

- NHEERL’s Mission and goals help EPA identify and understand the processes that affect our health and environment, and evaluate the risks that pollution poses to humans and ecosystems.

High Priority Research Areas

- Human Health
- Particulate Matter
- Drinking Water
- Clean Water
- Global Change
- Endocrine Disruptors
- Ecological Risk
- Pollution Prevention
- Homeland Security
**Experimental Toxicology Division**

- ETD conducts multidisciplinary research to improve the scientific basis of risk assessment for pulmonary, cardiovascular, hepatic, renal, and immunotoxicity
- Research facilitates the use of pharmacokinetic data in the risk assessment process
- Animal Inhalation Exposure Facility allows researchers to study the health effects of gases, vapors, and aerosols

**Animal Inhalation Exposure Facility Team**

- Performs inhalation exposure studies of gases, vapors, and aerosols including real world particulate matter (PM), and combustion emissions (e.g. fuel oil, natural gas, coal, diesel)
- Conducts air PM sampling, collection, and characterization
- Current projects include studies of concentrated real world PM air pollutants - and the role of size and components - on cardiopulmonary disease
Inhalation Exposure Studies of Concentrated Air Particles

- Determine health effects of “real world, real time” PM on cardio-pulmonary systems of various animal models
- Simultaneous real time exposures using multiple modes of concentrated ambient air PM
  - UCAPs – Ultra-fine (μf) mode aerosols (< 0.3 μm)
  - CAPs - Fine mode aerosols (0.3<X< 2.5 μm)

AIEF UCAPs/CAPs Small Animal Exposure Systems

- 0.3 m³ stainless steel and glass chambers for Ultra-fine PM, fine PM, and control groups
- Exposure chamber atmosphere monitoring, characterization, and control
- “Real time, real world” ambient air particles (not resuspended or laboratory generated)
- State-of-the-art particle growth and Slit Virtual Impactor particle concentrating technology
AIEF UCAPs/CAPs Small Animal Exposure Systems

- PM size fractionating eliminates incoming particles larger than PM$_{10}$, PM$_{2.5}$ and PM$_{0.3}$
- Specialized equipment concentrates remaining particles with minimal effect on particle chemistry
- Monitoring instruments measure and characterize atmosphere delivered to animals
- Repeated exposures, 6 hr/d, 5 d/wk, 13 wks
- Ambient weather station

PM Delivery System

- 10,000 Lpm ambient air containing PM drawn into size selective inlet (SSI) impactors
- Entering ambient PM size fractionated by SSIs to <2.5 μm
- 5000 Lpm each delivered to 2 different particle concentrating systems
- Slit Virtual Impactor (SVI) technology used to concentrate PM for independent, simultaneous UCAPs and CAPs studies
Ultra-fine PM Concentrating Equipment

- SVI technology is not directly effective on ultra-fine PM, therefore, requires particles <0.3 µm be grown to >1 µm for concentrating.
- Concentrating effect optimized at vapor super saturation ratio, \( S_r \approx 3.0 \).
- Supersaturated water vapor chamber grows µf PM to >1.5 µm in seconds.
- Multistage SVIs concentrate grown PM >40 X.
- Reshaper dries particles to original size and SSO eliminates PM > 0.3 µm prior to delivery to chamber.

UCAPs Schematic
Slit Virtual Impactor
**Slit Virtual Impactor**

- Computerized electronic monitoring and data recording of ambient meteorological, process, system, and chamber variables
  - Ambient meteorological conditions for entering air
  - >80 critical conditions including temp., RH, pres., flow, and PM monitored in real time
  - >30 critical variables controlled either automatically or manually
  - Instrument data backed up to multiple locations daily
- Regular manual data entry as backup to electronic data monitoring
- >95% electronic records, moving towards 100%
DASYLab Monitoring

HUCAPs Monitoring
Particle Monitoring

- Ambient and Chamber atmospheres monitored by continuous filter samples and electronic instruments for meteorological conditions and pollutant levels
- Filters provide mass concentration in $\mu$g/m$^3$
- SMPS, APS, DustTrak, P-Trak provide PM sizing ($\mu$m) and concentration (#/cc and $\mu$g/m$^3$)

System Validation

- Devices including T, RH, flow, particle sizing and concentration monitors, and balances were audited and performance was routinely verified
- Chamber aerosol distribution testing insured consistent dosing of all test animals
- Certified weights, standard and field blank filters validated balances daily
System Validation

- Instrument checks recommended by manufacturers performed daily to verify zero and span
- Collocated filters and chemical analysis procedures validate PM instruments
- Concentrating equipment was extensively characterized by preliminary testing

Electronic Records

- Electronic records developed where possible
- Notes and activities directly entered, recorded in files
- HUCAPs ADP controls allowed operators to monitor and adjust system parameters in real time to maintain optimal Sr and PM concentrating effects
- Process variables and chamber conditions recorded every 3 min.
Electronic Records

- DASYLab process monitoring software tracked and recorded T, RH, flow, press, and PM concentrations at 24 locations
- 9 Aerosol instruments tracked and recorded chamber and inlet PM parameters every 3 min.
- All electronic files were backed up to multiple locations including network servers daily

Redundancy

- Consistent exposures, reliable operations, minimal lost exposure time, equipment and process safeties, recoverable data
- Critical systems or measurements backed up with redundant equipment or alternative measurement techniques
- Examples include backup vacuum pumps, recoverable data such as chemical analysis of filters to backup balance measurements, DustTrak backup for filters, P-Trak backup for SMPS and APS
- Manual data entry as automatic data backup
Exposure Results

- Completed 6 hr/d, 5 d/wk, 13wks of exposures with just 2 hrs of 1170 hrs scheduled exposure time lost
- UCAPs concentrations up to \(5.0 \times 10^5\) #/cc, 500 ug/m\(^3\), ~80 nm # size, ~170 nm mass size, Avg. Mass X factor ~42.6 X
- CAPs concentrations up to 600 ug/m\(^3\), ~900 nm, Avg. Mass X factor ~25.5 X
- Post exposure chemical analysis of ~1000 filter samples and health effects results pending

Effective QC Practices

- Preliminary systems validation
- Survey of lab practices by QAM
- OPs backed up by detailed check lists completed daily
- Daily instrument QC checks
- Daily double checks of filter data sheets and activities entries
- Filter systems (sample port, holder, vacuum line, meter, valve, data sheet) color coded for location and sample ID
Effective QC Practices

- Multiple alternative measurement techniques
- Daily file backups, multiple locations
- Ongoing routine systems maintenance based on system performance tracking
- Excellent staff communications and routine planning meetings/discussions
- Backup staffing coverage through cross training of staff in all critical areas and tasks

Check lists

- Operations Status – allowed staff to track when various processes were completed so exposures could start
- Filter Sampling – insured filter samples were properly setup, and documentation completed
- Instrument Setup and QC checks – verified instrument performance daily prior to exposures
- Exposure Operations - ensured all aspects of OPs were followed, completed, and data were properly recorded and backed up
Exposure Operations

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Operations Status

HUCAPs Boiler Service
Filter Samples

Instrument Operations
Exposure Operations

Chamber Systems
Filter Sample Data Form