APPENDIX AVAILABLE ON THE HEI WEB SITE

Communication 17


Joe L. Mauderly and Jacob D. McDonald

Appendix C. Protocol Amendments

Note: Appendices Available on the Web may appear in a different order than in the original Investigators’ Report, and some remnants of their original names may be apparent. HEI has not changed the content of these documents, only the letter identifier.

Appendix C was originally Appendix B

Correspondence about Appendices B, C, and D may be addressed to Dr. Jacob D. McDonald, Lovelace Respiratory Research Institute, 2425 Ridgecrest Drive, S.E., Albuquerque, NM 87108; e-mail: jmcdonal@lrri.org.

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This appendix was reviewed by external reviewers. It was not reviewed by the HEI Health Review Committee and did not undergo the HEI editing and production process.

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APPENDIX B

Protocol Amendments
Protocol Amendment

ADVANCED COLLABORATIVE EMISSIONS STUDY (ACES): PHASE 3A

LRRI Protocol Number: FY08-147

Sponsor: Health Effects Institute (HEI)
101 Federal Street, Suite 500
Boston, MA 02110

Testing Facility: Lovelace Respiratory Research Institute (LRRI)
Inhalation Toxicology Laboratory
2425 Ridgecrest Dr. SE
Albuquerque, NM 87108
Courier:
Bldg 9217, Area Y
KAFB East
Albuquerque, NM 87115

Study Director: Jacob D. McDonald, PhD
Scientist
Lovelace Respiratory Research Institute

Protocol Amendment Approval:

[Signature] 7/8/09
LRRI Study Director: Jacob D. McDonald, PhD  Date

[Signature] 7/8/09
LRRI Principal Investigator: Joe L. Mauderly, DVM  Date

[Signature] 6/29/09
HEI Sponsor Representative: Annemoon van Erp, PhD  Date
Amendment A. Changes to text noted in italics.

7.0 CHARACTERIZATION OF EXHAUST AND INHALATION EXPOSURE SYSTEM

Table 2 summarizes the tests, objectives and number of trials for each set of tests for the characterization of the ACES engine. The characterization will be conducted subsequent to the change-out of the surrogate engine for Engine B. Once in place, exhaust characterization of the regulated pollutants will be measured for modes 1, 3, and 5 of the steady state cycle, the FTP cycle, and the ACES phase 3 cycle. Assessment of detailed chemical composition, including all of the measurements summarized in Table 3 will be conducted at a dilution set to achieve 4.2 ppm NO₂. The rationale and a description for each test are provided below. All of the testing will utilize the 16 hour transient cycle that was developed for the ACES program. Measurements will all be conducted in a single H-2000 exposure chamber, using one that is currently installed for use at the highest exposure concentration. This was the type of chamber used at SwRI. Chamber environmental conditions (temperature and humidity) will be monitored during each test, along with engine and trap regeneration conditions.

To ensure system robustness, Engine B will be operated a minimum of 2 weeks without fail prior to exchange with Engine B’. Once Engine B’ is in place an initial engine map on the 16 hr and FTP cycle will be conducted to ensure it meets regression criteria. Subsequent to acceptable engine cycle performance, Engine B’ will be characterized for Tests 1, 2 and 7 in Table 2. Engine B’ will be operated without fail for a minimum of 2 weeks to pass robustness.

<table>
<thead>
<tr>
<th>Test</th>
<th>Objective</th>
<th>No. of Trials</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Exhaust characterization on steady state and FTP cycles</td>
<td>Evaluate exhaust characteristics to verify proper engine performance</td>
<td>3/cycle condition</td>
<td>Only regulated gases, particle mass and size distribution</td>
</tr>
<tr>
<td>2. Determine composition and environmental conditions at dilution rate set to achieve 4.2 ppm NO₂</td>
<td>Compare SWRI exposure chamber composition to LRRI exposure chamber composition</td>
<td>3</td>
<td>SWRI chamber characterization used the 40 x dilution rate. Only regulated gases, particle mass and size distribution</td>
</tr>
<tr>
<td>3. Determine minimum allowable dilution rate</td>
<td>Define highest concentration in exposure chamber at which temperature within the chamber is &lt; 27°C (target 24°C average temperature)</td>
<td>Iterative</td>
<td>Dilution rate must result in proper temperature. NO₂ and CO may also be considered as limiting factors.</td>
</tr>
<tr>
<td>4. Determine chamber atmosphere composition at</td>
<td>Verify repeatability of composition and environmental</td>
<td>3</td>
<td>Will measure all components in Table</td>
</tr>
<tr>
<td>dilution to achieve 4.2 ppm NO₂</td>
<td>profile at proposed minimum allowable dilution</td>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------------------</td>
<td>----</td>
<td></td>
</tr>
<tr>
<td>5. Determine chamber performance at dilution to achieve 4.2 ppm NO₂</td>
<td>Pre-validation to characterize T90, chamber homogeneity and repeatability</td>
<td>3</td>
<td>Only regulated gases, particle mass and size distribution</td>
</tr>
<tr>
<td>6. Determine chamber atmosphere composition at dilution to achieve 0.1 and 0.8 ppm NO₂</td>
<td>Define atmosphere proportionality with dilution rate for key constituents</td>
<td>3</td>
<td>Only regulated gases, particle mass and size distribution</td>
</tr>
<tr>
<td>7. Determine particle number count and size distribution in chamber and prior to exposure chamber at dilution set to achieve 4.2 ppm NO₂</td>
<td>Assess particle changes as a result of inhalation exposure chamber and aerosol transit lines</td>
<td>3</td>
<td>Determine with steady state and FTP cycles</td>
</tr>
</tbody>
</table>

7.1 Exhaust Characterization on Steady State and FTP Cycles

Exhaust characterization will be conducted to measure NOx, NO₂, CO₂, non-methane hydrocarbons, particle number and size distribution after primary dilution from the engine. This will be conducted in modes 1, 3 and 5 of the steady state engine cycle and with the FTP cycle. Exhaust will be extracted from the primary dilution tunnel and further diluted with clean compressed air to achieve a temperature < 90 °F. *This secondary dilution will occur prior to the exposure chamber, where the samples will be collected. Particle mass will be measured with a Dekati Mass Monitor and Fast Mobility Particle Sizer.* FTP cycle measurements will be conducted to ensure that the start and end of the sample collection occurs at the same point in the engine cycle.

7.3 Determine Minimum Allowable Dilution Rate

*The target concentration at the high exposure level has been defined as a dilution to achieve 4.2 ppm. A maximum dilution rate determination is not required.*

7.4 Determine Composition of the Chamber Atmosphere at the Dilution Rate set to Achieve 4.2 ppm NO₂

*Inhalation exposure atmosphere characterization will be conducted at a dilution set to achieve 4.2 ppm NO₂. Chamber composition and environmental conditions will be assessed in detail by all measurements defined in Table 3. Speciated hydrocarbons (gas and semi-volatile) will be collected and analyzed in two of the three tests. Measurements will be conducted during the entire 16 hour transient cycle.*

7.6 Determine Composition in the Chamber at Additional Target Dilutions

*Particle mass, size and the regulated gases will be assessed at dilutions set to achieve 0.8 and 0.1 ppm NO₂. These tests will allow assessment of the proportionality of atmosphere composition with increases in dilution.*