STATE OF CALIFORNIA
STANDARD AGREEMENT
STD 213 (Rev 06/03)

AGREEMENT NUMBER
06-104-600-0
REGISTRATION NUMBER

1. This Agreement is entered into between the State Agency and the Contractor named below:

STATE AGENCY'S NAME (Also referred to as Cal/EPA or the State)
California Environmental Protection Agency

CONTRACTOR'S NAME (Also referred to as Contractor)
The Regents of the University of California, Berkeley

2. The term of this Agreement is: July 1, 2006 through June 30, 2011 **(Contract effective upon contract start date or upon approval by DGS whichever is later, and no work shall begin before contract effective date).**

3. The maximum amount of this Agreement is: $ 1,115,000
One Million One Hundred Fifteen Thousand Dollars.

4. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of the Agreement.

Exhibit A – Scope of Work	8 pages
Exhibit B – Budget Detail and Payment Provisions	5 pages
Exhibit B, Attachment I – Budget (Year 1)	1 page
Exhibit B, Attachment II – Budget (Year 2)	1 page
Exhibit B, Attachment III – Budget (Year 3)	1 page
Exhibit B, Attachment IV – Budget (Year 4)	1 page
Exhibit B, Attachment V – Budget (Year 5)	1 page
Exhibit C* - General Terms and Conditions	GIA 101

See Exhibit D, Provision 1 for additional incorporated exhibits.

Items shown with an Asterisk (*) are hereby incorporated by reference and made part of this agreement as if attached hereto. These documents can be viewed at www.ols.dgs.ca.gov/Standard+Language

IN WITNESS WHEREOF, this Agreement has been executed by the parties hereto.

CONTRACTOR

CONTRACTOR'S NAME *(if other than an individual, state whether a corporation, partnership, etc.)*
The Regents of the University of California, Berkeley

BY *(Authorized Signature)* — DATE SIGNED *(Do not type)*: 11.20.06

PRINTED NAME AND TITLE OF PERSON SIGNING
BRIAN C. DONOHUE, BUSINESS CONTRACTS OFFICE

ADDRESS
University of California Berkeley
Berkeley, CA 94720-1250

STATE OF CALIFORNIA

AGENCY NAME
California Environmental Protection Agency

BY *(Authorized Signature)* — DATE SIGNED *(Do not type)*: 12-01-2006

PRINTED NAME AND TITLE OF PERSON SIGNING
Donald E. Owen, Jr., Assistant Secretary

ADDRESS
1001 I Street, Sacramento, CA 95814

California Department of General Services Use Only

APPROVED
DEC 15 2006
DEPT OF GENERAL SERVICES

☐ Exempt per:

STANDARD AGREEMENT (STD 213) – 2ND PAGE

California Air Resources Board – Contract Number: 06-822

Socorro Watkins, Chief
Business Management Branch

12/5/06
Date

Department of Pesticide Regulation – Contract Number: 06-0099C

JoAnne Payan, Assistant Director

12/7/06
Date

Department of Toxic Substances Control – Contract Number: 06-T3170

Sandra Poindexter, Branch Chief
Contracts & Business Management Branch

12/5/06
Date

Office of Environmental Health Hazard Assessment – Contract Number: 06-E0021

Margie Leary, Deputy Director, Admin. Support Services

12/5/06
Date

State Water Resources Control Board – Contract Number: 06-104-600-0

Esteban Almanza, Deputy Director
Division of Administrative Services

12/5/06
Date

Integrated Waste Management Board – Contract Number: IWM06057

Mark Leary, Executive Director

December 5, 2006
Date

Exhibit A
Scope of Work

1. Service Overview

The Regents of the University of California, Berkeley, agrees to provide the following services to the California Environmental Protection Agency (Cal/EPA).

The Contractor must provide peer review services for the scientific basis of any rule proposed by Cal/EPA, upon request.

2. Project Representatives

A. The project representatives during the term of this agreement will be:

Cal/EPA	The Regents of the UC, Berkeley
Dr. Gerald W. Bowes, Project Director Telephone: (916) 341-5567 Fax: (916) 341-5463 E-mail: gbowes@waterboards.ca.gov	Brian Donohue, Business Contract Administrator Business Contracts Office Telephone: (510) 642-3128 Fax: (510) 642-8604 E-mail: donohue@berkeley.edu

B. Direct all inquires to:

Cal/EPA	The Regents of the UC, Berkeley
Attention: Dr. Gerald W. Bowes Toxicology and Peer Review Section State Water Resources Control Board Division of Water Quality 1001 I Street Sacramento, CA 95814 Telephone: (916) 341-5567 Fax: (916) 341-5463 E-mail: gbowes@waterboards.ca.gov	Attention: Professor Inez Fung, Project Director Telephone: (510) 643-9367 Fax: (510) 642-4612 E-mail: ifung@berkeley.edu Attention: Dr. Sharima Rasanayagam, Exe. Dir. Telephone: (510) 642-1385 Fax: (510) 642-4612 E-mail: sharima@berkeley.edu The Regents of the UC, Berkeley Berkeley Institute of the Environment MC 1250 University of California, Berkeley Berkeley, CA 94720-1250

C. Either party may make changes to the information above by giving 10 days written notice to the other party. Said changes shall not require an amendment to this agreement.

Exhibit A
Scope of Work

3. Background

The services described herein refer to those to be performed for the Cal/EPA. In 1991, a total of six Boards, Departments, and an Office were placed under the Cal/EPA "umbrella" to create a cabinet level voice for the protection of human health and the environment. The six are identified below.

The services respond both to the statute mandate for external review, as well as Cal/EPA internal guidance identifying categories of subjects for potential review that are separate from the legislative mandate.

4. Statute Requirement for External Scientific Peer Review

A. In 1997, the Governor signed into law Senate Bill 1320 (Sher 1997). The language is now incorporated into Health and Safety Code Section 57004. The statute requires all Cal/EPA organizations to submit for external scientific peer review all proposed rules that have a scientific basis or components.

B. Specifically, the statute notes that no Cal/EPA organization shall take any action to adopt the final version of a rule unless several conditions are met. One of these is that "The board, department or office submits the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation."

C. The language from Health and Safety Code Section 57004 that relates to external scientific peer review is in Exhibit F, Attachment A.

5. Cal/EPA Organizations Affected by Statute Requirements by Peer Review

The Agreement shall provide for identifying qualified reviewers, with no conflict of interest, upon request for reviewing the scientific basis and scientific components of rules proposed by the six Cal/EPA organizations listed below:

A. Air Resources Board
B. Department of Pesticide Regulation
C. Department of Toxic Substances Control
D. Office of Environmental Health Hazard Assessment
E. State Water Resources Control Board
(including nine Regional Water Quality Control Boards)
F. Integrated Waste Management Board
(To be augmented in a later date. A formal amendment is required)

Exhibit A
Scope of Work

6. Additional Work Products which are Valid Subjects for External Peer Review

A. This Agreement also shall provide external peer review of certain work products not subject to review by Health and Safety Code Section 57004. Reviewer candidates for these work products must meet the same requirements regarding no conflict of interest as those candidates identified for review of proposed rules.

B. The Cal/EPA document titled, *Unified California Environmental Protection Agency Policy and Guiding Principles for External Scientific Peer Review*, dated March 13, 1998, identifies such categories of work products (pp 6-7), examples of which are given below. The distinguishing feature of these is that they address important scientific topics which would have statewide significance.

1) *Products that Address Emerging or Controversial Issues, Have Significant Cross-Media Implications, or Establish a Significant Precedent*
e.g., Application of new scientific findings in hazardous waste classification.
e.g., Risk assessment methods, development, and findings. (for example, impacts concerning children or new environmental chemical fate transport models that substantially modify risk outcomes).

2) *Scientific Products that Support Regulations, Standards, or Rules*
e.g., Critical technical guidance documents for the regulated community.

3) *New Decision Criteria, Analytical Tools, or Models of Significance or Changes in Assessment Methodologies to be Used Routinely in Risk Assessment.*
e.g., Significant new or revised models and other techniques designed to predict exposure, simulate transport, etc.
e.g., Changes or innovations in analytical measurement techniques for pollutants.

7. Work Products Not Requiring Peer Review

The Cal/EPA Guiding Principles document referred to above notes that there are several circumstances where peer review is not required under Health and Safety Code Section 57004. Peer review is not required for permits, variances, enforcement actions, and similar types of activities, unless they are accomplished through rulemaking.

8. Contractor Responsibility for Receiving and Acting Upon Requests for External Peer Review

The Contractor shall establish a mechanism for receiving and acting upon requests for external peer review. The Contractor's responsibility is to identify reviewer candidates with scientific expertise in the proposed rule or work product to be reviewed, and submit their names and Conflict of Interest Disclosure to an independent entity to be identified by Cal/EPA for verification of their declarations.

Exhibit A
Scope of Work

Cal/EPA will be responsible for contracting with the independent entity and for determining and paying its fees. The independent entity will be solely responsible for verification of Conflict of Interest Disclosures.

Professor Inez Fung, Co-Director, University of California, Berkeley Institute of the Environment (BIE), shall be the Project Director (Principal Investigator) for this Agreement.

A. Options for responding to the request for external peer review include, but are not restricted to those listed below. Professor Fung will be responsible for the decision for which option or options to follow.

   1) Several individuals would be identified to address the needs of the six Cal/EPA organizations, respectively. Each individual would be responsible for identifying reviewer candidates for a particular Cal/EPA organization.

   2) A panel would be established. Panel members' expertise collectively would cover the range of scientific responsibilities and needs of Cal/EPA. The panel, through a mechanism which it would develop, would identify suitable reviewer candidates for the six requesting Cal/EPA organizations.

   3) A combination of the above. As in 1) above, individuals would be assigned major responsibility for responding to the requests from a particular Cal/EPA organization. However, with this option, each could call upon other individuals in this group (or panel, loosely defined in this context) for assistance in candidate identification, especially for review of proposals or work products that have cross-media implications.

   Note: With any option a "back-up" individual may be necessary to identify reviewer candidates in the absence of the individual originally given the responsibility for a particular Cal/EPA organization.

B. The Contractor shall ensure that each reviewer candidate complete and sign a Conflict of Interest (COI) Disclosure form. The form shall be the same as one which has been used by the University based on a National Academy of Sciences model.

C. The Contractor shall review the existing COI Disclosure form with respect to its efficiency of the use and extent of coverage of potential COI issues that should be reviewed. The Contractor shall make recommendations for change, if deemed necessary, to enhance the efficiency and effectiveness of this form. Use of any new or revised form shall be mutually agreed upon by the Contractor and Cal/EPA Project Director.

Exhibit A
Scope of Work

9. The External Peer Review Process

A. The external peer review process shall be in accordance with the guidelines established for the State and Regional Water Boards, an organization within Cal/EPA. These are now titled *California Environmental Protection Agency (Cal/EPA) External Scientific Peer Review Guidelines. Update November 2006. Gerald W. Bowes.* These guidelines are in Exhibit F attached to this agreement. The steps are outlined here in Paragraph 9, sub-paragraph A. through L. These guidelines have been the implementing mechanism for acquiring external peer reviewers for the State and nine Regional Water Boards through a peer review contract established with the University of California, Berkeley, Professor David Jenkins, Project Director (Principal Investigator). For the purpose of this Agreement, the Project Director (Principal Investigator) shall be Professor Inez Fung, Co-Director University of California, BIE. The State Water Board contract with Professor Jenkins shall continue to serve as the principal vehicle for obtaining external peer reviewers for that organization for proposed science-based rules subject to Health and Safety Code Section 57004. Water Board work products that are not proposed rules, as noted in section 6 above shall be submitted for reviews through the Agreement with BIE.

B. For the purpose of this Agreement, Dr. Gerald W. Bowes shall serve as the Cal/EPA Project Director. All requests for external reviewers shall be sent to him by the Cal/EPA organizations. Professor Inez Fung, BIE, shall be the Project Director (Principal Investigator) for the University.

C. In Exhibit F, the guidelines include a section, *Submitting the Request for External Reviewers.* It describes the contents of the letter of request, including three attachments from the Cal/EPA organizations to the Cal/EPA Project Director. The second of these attachments provides focus for the reviewers for their review of the proposed science-based rule or work product. Both proposed rules and work products must meet the test of being based on sound scientific principles, regardless of whether the material being reviewed is subject to the statute requirement for external scientific peer review.

D. **The Cal/EPA Project Director has no conflict of interest with respect to the request for external peer reviewers, and is a neutral party with respect to the subject of the proposal to be reviewed and has no organizational constraints that would limit this neutrality.**

E. The Cal/EPA Project Director independently reviews the draft request and recommends changes as necessary for clarity and content. The final, mutually agreed upon request is sent to the University Project Director from the Cal/EPA Project Director.

F. The University Project Director identifies and contacts reviewer candidates. Each candidate willing to perform the review must complete a Conflict of Interest Disclosure form and submit it to University Project Director who will forward to the independent entity identified by Cal/EPA for review. The independent entity notifies the University and Cal/EPA Project Directors of its decision after veting each candidate's disclosure form. The Cal/EPA Peer Review Project Director, through a written communication, transmits the names of approved candidates to the

Exhibit A
Scope of Work

requesting organization's representative who signed the request for external reviewers. Contact and biographical information also are provided to the requesting organization.

G. From this point forward, all subsequent communications are directly between the Cal/EPA organization initiating the request for reviewers and the reviewers. Cal/EPA and University Project Directors do not participate in these communications with the exception where the University Project Director may be self-designated as a reviewer because of expertise appropriate for the proposal. (In this circumstance, the University Project Director also must complete the COI Disclosure form, and be approved as a reviewer by the independent entity.

H. The approved reviewers must be contacted immediately by the requesting organization, confirming the date of availably of material to be reviewed, the preferred mailing address and means of communication. (Some reviewers prefer all material to be sent electronically).

I. The material to be sent to reviewers includes:

1) Cover letter requesting the review;
2) The three attachments which accompanied the original letter of request for reviewers (Attachment 1 is the Plain English Summary of the proposed rule (or work product); Attachment 2 highlights the essential scientific topics to be reviewed, and commented upon; Attachment 3 lists the names and affiliations of those who participated in development of the proposal; Health and Safety Code Section 57004 does not allow these individuals to serve as reviewers); and
3) Material to be reviewed, including proposed implementation language for the scientific basis or scientific components of the rule or work product.

J. The suggested 30-day review period can be changed with mutual agreement between the Cal/EPA organization and the reviewer(s).

K. **Discussions between staff and reviewers are not permitted. There is one exception-the reviewers' need for clarification of certain aspects of the documents being reviewed, where this need has been expressed. Questions and responses shall be written, for the record. E-mail is acceptable.**

L. Upon completion of the assignment, reviewers shall send one full set copy of the peer reviews directly to the Cal/EPA requesting organization and one full set copy to the University Project Director. The reviewers shall **only** send their invoices directly to the University Project Director for review/approval, and not to the Cal/EPA organizations. The University Project Director will authorize payment for completed reviews.

Exhibit A
Scope of Work

10. Subcontractor Requirements

A. Prior written authorization will be required before the Contractor enters into or is reimbursed for any subcontract for services costing $5,000 or more. Except as indicated in paragraph A3) herein, when securing subcontracts for services exceeding $5,000, the Contractor shall obtain at least three bids or justify a non-competitively bid award.

1) The Contractor must provide in its request for authorization, all particulars necessary for evaluating the necessity or desirability of incurring such cost.

2) The State may identify the information needed to fulfill this requirement.

3) Subcontracts performed by the entities or for the service types listed below are exempt from the bidding and sole source justification requirements:

a) A local governmental entity or the federal government,
b) A State college or university from any State,
c) A Joint Powers Authority,
d) An auxiliary organization of a California State University or a California Community College,
e) A Foundation organized to support the Board of Governors of the California Community Colleges,
f) An auxiliary organization of the Student Aid Commission established under Education Code § 69522,
g) Entities of any type that will provide subvention aid or direct services to the public,
h) Entities and/or service types identified as exempt from advertising in State Administrative Manual Section 1233 subsection 3. View this publication at the following Internet address: http://sam.dgs.ca.gov,
i) Other academic institutions of higher education, or consortia of academic institutions of higher education (including private universities and educational institutes)

B. Cal/EPA reserves the right to approve or disapprove the selection of subcontractors and with advance written notice, require the substitution of subcontractors and require the Contractor to terminate subcontracts entered into in support of this agreement.

1) Upon receipt of a written notice from Cal/EPA requiring the substitution and/or termination of a subcontract, the Contractor shall take steps to ensure the completion of any work in progress and select a replacement, if applicable, within 30 calendar days, unless a longer period is agreed to by Cal/EPA.

C. Actual subcontracts (i.e., written agreement between the Contractor and a subcontractor) of $5,000 or more are subject to the prior review and written approval of Cal/EPA. Cal/EPA may, at its discretion, elect to waive this review. All such Waivers shall be confirmed in writing by Cal/EPA.

Exhibit A
Scope of Work

D. Contractor shall maintain a copy of each subcontract entered into in support of this agreement and shall, upon request by Cal/EPA, make said copies available for approval, inspection, or audit.

E. Cal/EPA assumes no responsibility for the payment of subcontractors used in performance of this agreement. Contractor accepts sole responsibility for the payment of subcontractor used in performance of this agreement.

F. The Contractor is responsible for all performance requirements under this agreement even though performance may be carried out through a subcontract.

G. The Contractor shall ensure that all subcontracts for services include provision(s) requiring compliance with applicable terms and conditions specified in this agreement.

H. The Contractor agrees to include the following clause, relevant to record retention, in all subcontracts for services:

"(*Subcontractor Name*) agrees to maintain and preserve, until three years after termination of (*Agreement Number*) and final payment from Cal/EPA, to permit Cal/EPA or any duly authorized representative to have access to, examine or audit any pertinent books, documents, papers and records related to this subcontract and to allow interviews of any employees who might reasonably have information related to such records."

I. Unless otherwise stipulated in writing by Cal/EPA, the Contractor shall be the subcontractor's sole point of contact for all matters related to performance and payment under this agreement.

Exhibit B
Budget Detail and Payment Provisions

1. Invoicing

A. For services satisfactorily rendered according to the scope of work and the terms, conditions and exhibits of this agreement, and upon receipt an approval of the invoices, Cal/EPA agrees to compensate the Contractor for actual expenditures incurred in accordance with the budget(s) attached hereto.

B. Invoices shall include the Agreement Number, Cal/EPA organization name, and shall be submitted in triplicate not more frequently than monthly in arrears to:

Dr. Gerald W. Bowes, Project Director
State Water Resources Control Board
Toxicology and Peer Review Section
Division of Water Quality
1001 I Street
Sacramento, CA 95814

C. Invoices shall:

1) Be prepared on Contractor letterhead. If invoices are not on produced letterhead invoices must be signed by an authorized official, employee or agent certifying that the expenditures claimed represent actual expenses for the service performed under this contract.
2) Bear the Contractor's name as shown on the agreement.
3) Bear Cal/EPA's organization name (see Exhibit A-Scope of Work, paragraph 5)
4) Identify the billing and/or performance period covered by the invoice.
5) Identify the reviewer's name and costs (subcontractor).
6) Itemize costs for the billing period in the same or greater level of detail as indicated in this agreement (Exhibit B, Attachment I, II, III, IV, and V). Subject to the terms of this agreement, reimbursement may only be sought for those costs and/or cost categories expressly identified as allowable in this agreement and approved by Cal/EPA.

2. Budget Contingency Clause

A. It is mutually agreed that if the Budget Act of the current year and/or any subsequent years covered under this Agreement does not appropriate sufficient funds for the program, this Agreement shall be of no further force and effect. In this event, the State shall have no liability to pay any funds whatsoever to Contractor or to furnish any other considerations under this Agreement and Contractor shall not be obligated to perform any provisions of this Agreement.

B. If funding for any fiscal year is reduced or deleted by the Budget Act for purposes of this program, the State shall have the option to either cancel this Agreement with no liability occurring to the State, or offer an agreement amendment to Contractor to reflect the reduced amount.

3. Payment

Exhibit B
Budget Detail and Payment Provisions

A. Costs under this agreement shall be computed in accordance with State Administrative Manual Sections 8752 and 8752.1.

B. **Reimbursement**

Costs under this agreement have been negotiated and reimbursement is limited to allowable costs incurred pursuant to the budget attachment(s). Said costs are inclusive of applicable charges including wages, salaries, fringe benefits, direct project demands and an indirect/overhead rate (if applicable) not to exceed the percentage rate indicated in the budget attachment(s).

4. Amounts Payable

A. The amounts payable under this agreement shall not exceed for the **Air Resources Board**:

1) $95,000 for the budget period of 07/01/06 through 06/30/07.
2) $95,000 for the budget period of 07/01/07 through 06/30/08.
3) $95,000 for the budget period of 07/01/08 through 06/30/09.
4) $95,000 for the budget period of 07/01/09 through 06/30/10.
5) $95,000 for the budget period of 07/01/10 through 06/30/11.

B. The amounts payable under this agreement shall not exceed for the **Department of Pesticide Regulation:**

1) $20,000 for the budget period of 07/01/06 through 06/30/07.
2) $20,000 for the budget period of 07/01/07 through 06/30/08.
3) $20,000 for the budget period of 07/01/08 through 06/30/09.
4) $20,000 for the budget period of 07/01/09 through 06/30/10.
5) $20,000 for the budget period of 07/01/10 through 06/30/11.

C. The amounts payable under this agreement shall not exceed for the **Department of Toxic Substances Control**:

1) $75,000 for the budget period of 07/01/06 through 06/30/07.
2) $75,000 for the budget period of 07/01/07 through 06/30/08.
3) $75,000 for the budget period of 07/01/08 through 06/30/09.
4) $75,000 for the budget period of 07/01/09 through 06/30/10.
5) $75,000 for the budget period of 07/01/10 through 06/30/11.

D. The amounts payable under this agreement shall not exceed for the **Office of Environmental Health Hazard Assessment**:

1) $10,000 for the budget period of 07/01/06 through 06/30/07.
2) $10,000 for the budget period of 07/01/07 through 06/30/08.
3) $10,000 for the budget period of 07/01/08 through 06/30/09.
4) $10,000 for the budget period of 07/01/09 through 06/30/10.
5) $10,000 for the budget period of 07/01/10 through 06/30/11.

Exhibit B
Budget Detail and Payment Provisions

E. The amounts payable under this agreement shall not exceed for the **State Water Resources Control Board (Nine Regional Water Quality Control Boards)**:

1) $23,000 for the budget period of 07/01/06 through 06/30/07.
2) $23,000 for the budget period of 07/01/07 through 06/30/08.
3) $23,000 for the budget period of 07/01/08 through 06/30/09.
4) $23,000 for the budget period of 07/01/09 through 06/30/10.
5) $23,000 for the budget period of 07/01/10 through 06/30/11.

F. All the Reimbursement above shall be made for allowable expenses up to the amount annually encumbered commensurate with the state fiscal year in which services are performed and/or goods are received.

5. Expense Allowability / Fiscal Documentation

A. Invoices, received from a Contractor and accepted and/or submitted for payment by the State, shall not be deemed evidence of allowable agreement costs.

B. Contractor shall maintain for review and audit and supply to Cal/EPA upon request if payments are questioned by the State Controller, adequate documentation of any questionable expenses claimed pursuant to this agreement to permit a determination of expense allowability.

C. If the allowability or appropriateness of an expense cannot be determined by the State because invoice detail, fiscal records, or backup documentation is nonexistent or inadequate according to generally accepted accounting principles or practices, all questionable costs may be disallowed and payment may be withheld by the State. Upon receipt of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed allowable.

D. If travel is a reimbursable expense, receipts must be maintained to support the claimed expenditures.

E. Costs and/or expenses deemed unallowable are subject to recovery by Cal/EPA. See provision #9 in this exhibit entitled, "Recovery of Overpayments" for more information.

Exhibit B
Budget Detail and Payment Provisions

6. Travel and Per Diem Reimbursement

Travel and per diem reimbursement shall be in accordance with University travel regulations and rates. Reimbursement for out-of-state travel requires prior written authorization by Cal/EPA Project Director who may either approve said travel in a budget exhibit or issue a letter of approval if such travel was not previously specified in an approved budget. A copy of the Contractor's approved travel rates shall be provided to Cal/EPA upon request.

7. Allowable Line Item Shifts

A. Either party may shift or re-budget line items and related detailed expenses appearing in each budget exhibit attachment, as stipulated herein. Budget changes requested/required by Cal/EPA shall be initiated by written notification to the Contractor.

B. Cumulative changes to budget detail, line item shifts or the re-budgeting of line item totals is allowed up to $25,000, or 10% of each annual budget total, whichever is greater, up to a cumulative annual maximum of $50,000 provided no annual budget total is increased or decreased.

Said budget changes shall not require prior Cal/EPA approval or a formal agreement amendment provided said budget changes do not alter any total budget exhibit amount or alter/affect performance of the scope of work.

C. Contractor initiated budget changes that exceed the limits specified in paragraph B herein or that alter/affect performance of the scope of work require prior written Cal/EPA notification and approval and the processing of a formal amendment to this agreement. The timing, method and manner of notifying Cal/EPA of said changes or requesting Cal/EPA approval shall be mutually agreed upon in writing by both parties. Cal/EPA may determine the format of said requests or provide a specific form for this purpose. If Cal/EPA does not indicate a specified format or form, the Contractor may devise its own, subject to Cal/EPA approval. Invoices reflecting expenses based on budgetary changes described herein may be temporarily held or reduced until proper Cal/EPA approval is obtained.

8. Federal Contract Funds

A. It is mutually between the parties that this agreement may have been written before ascertaining the availability of congressional appropriation of funds, for the mutual benefit of both parties, in order to avoid program and fiscal delays which would occur if the agreement were executed after that determination was made.

B. This agreement is valid and enforceable only if sufficient funds are made available to the State by the United States Government for the fiscal years covered by the term of this agreement. In addition, this agreement is subject to any additional restrictions, limitations, or conditions enacted by the Congress or any statute enacted by the Congress which may affect the provisions, terms or funding of this agreement in any manner.

Exhibit B
Budget Detail and Payment Provisions

C. It is mutually agreed that if the Congress does not appropriate sufficient funds for the program, this agreement shall be amended to reflect any reduction in funds.

D. Cal/EPA has the option to invalidate or cancel the agreement with 30-days advance written notice or to amend the agreement to reflect any reduction in funds.

9. Recovery of Overpayments

A. Contractor agrees that claims based upon a contractual agreement or an audit finding and/or an audit finding that is appealed and upheld, will be recovered by the State and/or Federal Government by one of the following options:

1) Contractor's remittance to the State of the full amount of the audit exception within 30 days following the State's request for repayment;
2) A repayment schedule, which is agreeable to both the State and the Contractor.

B. The State reserves the right to select which option will be employed and the Contractor will be notified by the State in writing of the claim procedure to be utilized.

C. Interest on the unpaid balance of the audit finding or debt will accrue at a rate equal to the monthly average of the rate received on investments in the Pooled Money Investment Fund commencing on the date that an audit or examination finding is mailed to the Contractor, beginning 30 days after Contractor's receipt of the State's demand for repayment, or commending on the date that an audit or examination finding is mailed to the Contractor, if applicable.

D. If the Contractor has filed a valid appeal regarding the report of audit findings, recovery of the overpayments will be deferred until a final administrative decision on the appeal has been reached. If the Contractor loses the final administrative appeal, Contractor shall repay, to the State, the over-claimed or disallowed expenses, plus accrued interest. Interest accrues from the Contractor's first receipt of State's notice requesting reimbursement of questioned audit costs or disallowed expenses.

Exhibit B, Attachment I
Budget
(Year 1)
(07/01/06 through 06/30/07)

Personnel

Total Personnel $ -0-

Fringe Benefits $ -0-

Operating Expenses

Total Operating $ 47,913

Equipment

Total Equipment $ -0-

Travel $ -0-

Subcontracts

Subcontractor: Professors at State, National Academy of Sciences, University of California, California State University, Scientific Institution of Higher Learning (any combination of those entities), Scientist or group of scientists of comparable stature and qualifications, or Private Universities.

*Payment to reviewers (730 hrs @ $200/hr) $ 146,000

Total Subcontracts $ 146,000

* ($200/hr is used as an average rate to be charged by reviewers, actual rates may vary)

Other Costs

Total Other Costs $ -0-

Indirect Costs (15% of Total Costs) $ 29,087

Total Costs $ 223,000

Exhibit B, Attachment II
Budget
(Year 2)
(07/01/07 through 06/30/08)

Personnel

Total Personnel $ -0-

Fringe Benefits $ -0-

Operating Expenses

Total Operating $ 47,913

Equipment

Total Equipment $ -0-

Travel $ -0-

Subcontracts

Subcontractor: Professors at State, National Academy of Sciences, University of California, California State University, Scientific Institution of Higher Learning (any combination of those entities), Scientist or group of scientists of comparable stature and qualifications, or Private Universities.

*Payment to reviewers (730 hrs @ $200/hr) $ 146,000

Total Subcontracts $ 146,000

* ($200/hr is used as an average rate to be charged by reviewers, actual rates may vary)

Other Costs

Total Other Costs $ -0-

Indirect Costs (15% of Total Costs) $ 29,087

Total Costs $ 223,000

Exhibit B, Attachment III
Budget
(Year 3)
(07/01/08 through 06/30/09)

Personnel

Total Personnel $ -0-

Fringe Benefits $ -0-

Operating Expenses

Total Operating $ 47,913

Equipment

Total Equipment $ -0-

Travel $ -0-

Subcontracts

Subcontractor: Professors at State, National Academy of Sciences, University of California, California State University, Scientific Institution of Higher Learning (any combination of those entities), Scientist or group of scientists of comparable stature and qualifications, or Private Universities.

*Payment to reviewers (730 hrs @ $200/hr) $ 146,000

Total Subcontracts $ 146,000

* ($200/hr is used as an average rate to be charged by reviewers, actual rates may vary)

Other Costs

Total Other Costs $ -0-

Indirect Costs (15% of Total Costs) $ 29,087

Total Costs $ 223,000

Exhibit B, Attachment IV
Budget
(Year 4)
(07/01/09 through 06/30/10)

Personnel

Total Personnel $ -0-

Fringe Benefits $ -0-

Operating Expenses

Total Operating $ 47,913

Equipment

Total Equipment $ -0-

Travel $ -0-

Subcontracts

Subcontractor: Professors at State, National Academy of Sciences, University of California, California State University, Scientific Institution of Higher Learning (any combination of those entities), Scientist or group of scientists of comparable stature and qualifications, or Private Universities.

*Payment to reviewers (730 hrs @ $200/hr) $ 146,000

Total Subcontracts $ 146,000

* ($200/hr is used as an average rate to be charged by reviewers, actual rates may vary)

Other Costs

Total Other Costs $ -0-

Indirect Costs (15% of Total Costs) $ 29,087

Total Costs $ 223,000

Exhibit B, Attachment V
Budget
(Year 5)
(07/01/10 through 06/30/11)

Personnel

Total Personnel $ -0-

Fringe Benefits $ -0-

Operating Expenses

Total Operating $ 47,913

Equipment

Total Equipment $ -0-

Travel $ -0-

Subcontracts

Subcontractor: Professors at State, National Academy of Sciences, University of California, California State University, Scientific Institution of Higher Learning (any combination of those entities), Scientist or group of scientists of comparable stature and qualifications, or Private Universities.

*Payment to reviewers (730 hrs @ $200/hr) $ 146,000

Total Subcontracts $ 146,000

* ($200/hr is used as an average rate to be charged by reviewers, actual rates may vary)

Other Costs

Total Other Costs $ -0-

Indirect Costs (15% of Total Costs) $ 29,087

Total Costs $ 223,000

Exhibit D
Additional Provisions

1. Additional Incorporated Exhibits

A. The following additional exhibits are attached, incorporated herein, and made a part hereof by this reference:

1) Exhibit D – Additional Provisions — 5 pages
2) Exhibit E – Copyright / Ownership / Use of Data — 5 pages
3) Exhibit F – External Scientific Peer Review Guidelines — 23 pages
   - Attachment A - Health and Safety Code Section 57004
   - Attachment B – Letter of Request for External Peer Reviewers for of Proposed Basin Plan Amendment to Adopt Site-Specific Ammonia Objectives
     - Attachment 1, Summary of Proposed Action
     - Attachment 2, Description of Scientific Issues to be addressed By Peer Reviewers
     - Attachment 3, Individuals Involved in Development of Basin Plan Amendment
   - Attachment C – Response Letter to Requesting Organization, Identifying External Peer Reviewers.

2. Contract Amendments

Should either party, during the term of this agreement, desire a change or amendment to the terms of this Agreement, such changes or amendments shall be proposed in writing to the other party, who will respond in writing as to whether the proposed changes/amendments are accepted or rejected. If accepted and after negotiations are concluded, the agreed upon changes shall be made through the State's official agreement amendment process. No amendment will be considered binding on either party until it is formally approved by both parties and the Department of General Services, if such approval is required.

3. Cancellation / Termination

A. This agreement may be cancelled or terminated without cause by either party be giving thirty (30) calendar days advance written notice to the other party. Such notification shall state the effective date of termination or cancellation and include any final performance and/or payment/invoicing instructions/requirements.

B. Upon receipt of a notice of termination or cancellation from Cal/EPA, Contractor shall take immediate steps to stop performance and to cancel or reduce subsequent contract costs.

C. Contractor shall be entitled to payment for all allowable costs authorized under this agreement, including authorized non-cancelable obligations incurred up to the date of termination or cancellation, provided such expenses do not exceed the stated maximum amounts payable.

Exhibit D
Additional Provisions

4. Dispute Resolution Process

If a dispute arises between the Contractor and CAL/EPA, the Contractor must seek resolution using the process outlined below.

A. The Contractor should first informally discuss the problem with CAL/EPA Project Director. If the problem cannot be resolved informally, the Contractor must direct the grievance together with any evidence, in writing, to the Cal/EPA' Assistant Secretary, Fiscal and Administrative Programs (FAP). The grievance must state the issues in dispute, the legal authority or other basis for the Contractor's position and the remedy sought. Cal/EPA' Assistant Secretary, FAP must render a decision within ten (10) working days after receipt of the written grievance from the Contractor. Cal/EPA' Assistant Secretary, FAP shall respond in writing to the Contractor indicating the decision and reasons therefore.

B. Unless otherwise stipulated in writing by CAL/EPA, all dispute, grievance and/or appeal correspondence shall be directed to the CAL/EPA Project Director.

C. There are organizational differences within CAL/EPA' funding programs and the management levels identified in this dispute resolution provision may not apply in every contractual situation. When a grievance is received and organizational differences exist, the Contractor shall be notified in writing by the CAL/EPA program Project Director of the level, name, and/or title of the appropriate management official that is responsible for issuing a decision at a given level.

D. Authority to terminate performance under the terms of this Agreement is not subject to appeal under this Section. All other issues including, but not limited to, the amount of any equitable adjustment, and the amount of any compensation or reimbursement which should be paid to the Contractor shall be subject to the disputes process under this Section. (PCC 10240.5, 10381, 22200 et seq, 40 CRF 31.70).

5. Mutual Indemnification

A. Cal/EPA and the Contractor shall mutually defend, indemnify and hold each other and their respective agencies, officers, employees, and agents harmless from and against any and all liability, loss, expense, attorneys' fees, or claims for injury or damages arising out of the performance of this agreement but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of either Cal/EPA or the Regents of the University of California.

B. It should be expressly understood that the obligations hereunder shall be conditioned upon this agreement being one that falls within the purview of Section 895 of the Government Code.

6. Confidentiality of Information

A. The Contractor and its employees, agents, or subcontractors shall protect from unauthorized disclosure names and other identifying information concerning persons either receiving

Exhibit D
Additional Provisions

services pursuant to this agreement or persons whose names or identifying information become available or are disclosed to the Contractor, his/her employees, agents, or subcontractors as a result of services performed under this agreement, except for statistical information not identifying any such person.

B. The Contractor and its employees, agents, or subcontractors shall not use such identifying information for any purpose other than carrying out the Contractor's obligations under this agreement.

C. The Contractor and its employees, agents, or subcontractors shall promptly transmit to Cal/EPA program project director all requests for disclosure of such identifying information not emanating from the client or person.

D. The Contractor shall not disclose, except as otherwise specifically permitted by this agreement or authorized by the affected individual, any such identifying information to anyone other than Cal/EPA without prior written authorization from Cal/EPA program project director, except if disclosure is required by State or Federal law.

E. For purposes of this provision, identity shall include, but not be limited to name, identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph.

7. Avoidance of Conflicts of Interest by Contractor

A. Cal/EPA intends to avoid any real or apparent conflict of interest on the part of the Contractor, subcontractors, or employees, officers and directors of the Contractor or subcontractors. Thus, Cal/EPA reserves the right to determine, at its sole discretion, whether any information, assertion or claim received from any source indicates the existence of a real or apparent conflict of interest under this agreement; and if a conflict is found to exist, to require the Contractor to submit additional information or a plan for resolving the conflict, subject to Cal/EPA review and prior approval.

B. Conflicts of interest include, but are not limited to:

1) An instance where the Contractor or any of its subcontractors, or any employees, officers, or director of the Contractor or any subcontractor has an interest, financial or otherwise, whereby the use or disclosure of information obtained while performing services under this agreement would allow for private or personal benefit or for any purpose that is contrary to the goals and objectives of this agreement.

2) An instance where the Contractor's or any subcontractor's employees, officers, or directors use their positions for purposes that are, or give the appearance of being, motivated by a desire for private gain for themselves or others, such as those with whom they have family, business or other ties.

Exhibit D
Additional Provisions

C. If Cal/EPA is or becomes aware of a known or suspected conflict of interest, the Contractor will be given an opportunity to submit additional information or to resolve the conflict. A Contractor with a suspected conflict of interest under this agreement will have five (5) working days from the date of notification of the conflict by Cal/EPA to provide complete information regarding the suspected conflict. If a conflict of interest under this agreement is determined to exist by Cal/EPA and cannot be resolved to the satisfaction of Cal/EPA, the conflict will be grounds for terminating this agreement. Cal/EPA may, at its discretion upon receipt of a written request from the Contractor, authorize an extension of the timeline indicated herein.

8. Site Inspection

The State, through any authorized representatives, has the right at all reasonable times to inspect or otherwise evaluate the work performed or being performed hereunder including subcontract supported activities and the premises in which it is being performed. If any inspection or evaluation is made of the premises of the Contractor or Subcontractor, the Contractor shall provide and shall require Subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the authorized representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

9. Documents, Publications and Written Reports

(Applicable to agreements over $5,000 under which publications, written reports and documents are developed or produced. Government Code Section 7550.)

Any document, publication or written report (excluding progress reports, financial reports and normal contract communications) prepared as a requirement of this agreement shall contain, in a separate section preceding the main body of the document, the number and dollar amounts of all contracts and subcontracts relating to the preparation of such document or report, if the total cost for work by non-employees of the State exceeds $5,000.

10. Debarment and Suspension Certification

(Applicable to all agreements funded in part of whole with federal funds.)

A. Contractor agrees to comply with the debarment and suspension requirements as found in 7 Code of Federal Regulations (CFR) Part 3107, 45 CFR Part 76, 40 CFR Part 32, or 34 CFR Part 85.

B. By signing this agreement, the Contractor certifies to the best of its knowledge and belief, that it and its principals:

1) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any federal department or agency;

2) Have not within a three-year period preceding this application/proposal/agreement been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public

Exhibit D
Additional Provisions

(Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

3) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph B.2) of this certification; and

4) Have not within a three-year period preceding this application/proposal/agreement had one or more public transactions (Federal, State, or local) terminated for cause or default.

5) Shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under federal regulations (i.e., 48 CFR part 9, subpart 9.4), debarred, suspended, declared ineligible, or voluntarily excluded from participation in such transaction, unless authorized by the State.

6) Will include a clause entitled, "Debarment and Suspension Certification" that essentially sets forth the provisions herein, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

C. If the Contractor is unable to certify to any of the statements in this certification, the Contractor shall submit an explanation to Cal/EPA program funding this contract.

D. The terms and definitions herein have the meanings set out in the Definitions and Coverage sections of the rules implementing Federal Executive Order 12549.

E. If the Contractor knowingly violates this certification, in addition to other remedies available to the Federal Government, the State may terminate this transaction for cause or default.

Exhibit E
Copyright / Ownership / Use of Data

I. Ownership of Intellectual Property and Materials

1. Ownership

The State, through this conveyance, shall be the owner of all rights, title and interest in, but not limited to, the copyright to all Works, as defined below, whether or not published and transferred. The State owns the copyright to any and all Works under this Agreement from the moment of creation. If, for any reason, the State is not deemed to be the owner of all rights, title and interest in the Work, then Contractor assigns through this agreement those rights to the State.

2. Definitions

A. "Copyright" is defined as protection for original works of authorship fixed in any tangible medium of expression, now known or later developed, from which those works can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.

B. "Work" is defined as any materials or products, as set forth in 17 U.S.C. 100 et seq. and related regulations and case law, created, produced conceptualized and fixed in a tangible medium of expression, developed, or delivered, and paid for under this Agreement (whether or not copyrighted). It includes preliminary and final products and any materials and information developed for producing those final products. Work does not include independent research projects as defined in **Conditions Applicable to Independent Research**.

3. License to State

For any product or material, except for data that is publicly available without restriction that is collected, created and fixed in a tangible medium of expression, produced, developed, or delivered and paid for under this contract that is not deemed a Work(s), the Contractor grants through this agreement to the State a royalty-free, non-exclusive, and irrevocable license throughout the world to reproduce, to prepare derivative works, to distribute copies, to perform, to display or otherwise use, duplicate or dispose of such Work in any manner for governmental purposes and to have or permit others to do so.

4. License Obligations of Contractor

The Contractor must indicate in the Scope of Work that the use of licensed products, including software products, are commercially available, can be purchased by the State, and can be performed on existing State equipment. Except as provided in the **Scope of Work**, the Contractor shall not use licensed materials without prior written permission of the State.

For Works that require the use of other copyright holders' materials, the Contractor shall furnish the names and addresses of all copyright holder(s) or their agent(s), if any, and the terms of any license(s) or usage granted, at the time of delivery of the Works.

Contractor shall obtain for the State a royalty-free, non exclusive and irrevocable license throughout the world to reproduce, to prepare derivative Works, to distribute copies, to perform,

to display or otherwise use, duplicate or dispose of these Works in any matter for government purposes and to have or permit others to do so for those Works for which the copyright is not assigned to the State or for which the Contractor failed to obtain copyright for the State, at Contractor's expense, Contractor may replace an infringing element with a comparable element that is non-infringing or does not violate the rights or interest of any person or entity with the State's written permission.

5. Subcontractors

Contractor shall require any agreements with other parties who will perform all or part of the Scope of Work under this Agreement to include clauses granting the State a copyright interest in any Work. Contractor shall require the other parties to assign those rights to the State on a form to be provided by the State.

6. Notice

Contractor shall include a notice of copyright supplied by the State in a place that can be visually perceived either directly or with the aid of a machine or device on all Work distributed under the terms of this Agreement and any reproductions of visual Works or text of these Works.

7. Noninterference of Rights of State

Contractor agrees that it has not knowingly granted and it shall not knowingly grant to any person or entity any right that would diminish, encumber or interfere with any of the rights granted to the State in this Agreement.

8. Remedies after Completion

If, after the completion and acceptance of the Work, the State becomes aware that the Work cannot be used because it would infringe upon the copyright, literary, dramatic, statutory, or common law rights, trademarks, or service marks of any third party, would infringe upon or violate the rights or interests of, or the rights of privacy of, a third party or would constitute libel or slander against a third party: as determined by the State, the Contractor shall provide the following remedies in consultation with the State and approval by the State.

A. Procure for the State a license as set forth in Article I, Paragraph 4. **License Obligations of Contractor**, above, to use that element of the Work, if available at a reasonable expense, or

B. Replace that element with the comparable element that is noninfringing or does not violate the rights or interest of any person or entity, or

C. Modify that element so it becomes noninfringing or does not violate the rights or interest of any person or entity, or

D. Remove any element that constitutes a libel or slander of any person or entity.

Exhibit E
Copyright / Ownership / Use of Data

Contractor makes no representations that it will maintain the capability to provide the remedies set forth in (a) through (d) above if the capability is dependent on maintaining the original computer software or hardware used to develop the element.

9. Materials

The State shall retain ownership of the original and all copies of the Work and the medium such as original artwork and negatives, print ready art or copy, computer diskettes, etc. Contractor shall make delivery of the original and copies within ninety (90) working days of request by the State or at termination, or expiration, of this Agreement or at the end of the fiscal year. Contractor may retain copies of the Work on file for audit purposes and for purposes identified in **License and Derivative Works**, of this Agreement.

II. License and Derivative Works

The State grants the Contractor a royalty-free, non-exclusive license to use, reproduce and disseminate a Work approved as satisfactory by the State and permission to create derivatives works and use, that Work in independent research projects, subject to the limitations **Conditions Applicable to Independent Research**, for noncommercial research and educational purposes.

III. Rights in Data

Notwithstanding any other provision of the Agreement or its Exhibits, Contractor understands and agrees that **Ownership of Intellectual Property and Materials** governs all ownership rights in data files, databases, or database systems.

IV. Conditions Applicable to Reports/Publications Deliverable to the State

1. The Contractor shall use data that is contained in all deliverable published reports or publications and provided by the State or collected or prepared under the Agreement by Contractor, except as provided in **Conditions Applicable to Independent Research**, under the following conditions:

   A. All data/research reports or publications shall contain (1) a disclaimer that credits any analysis, interpretations, or conclusions reached to the author(s) and not to the State, and (2) a statement on the biases in the data known to affect the report findings.

   B. The Contractor shall submit all deliverable public reports or publications to the State's Contract Manager for review, written comment and approval by the State, subject to requirements in **Satisfactory Deliverables**, at least ninety (90) calendar days before release of the deliverable public report or submission for publication or reproduction. The Contractor shall incorporate all of the comments of the State's Contract Manager insofar as possible, and the Contract Manager shall be informed of any comments which cannot be incorporated and why, so that any differences can be discussed before publication. The State review may make a determination that the technical descriptions of the data are consistent with those provided by the State and that all confidential information has been deleted or scrambled. Contractor shall delete or scramble all confidential information as required by the State. No deliverable public report or publication shall be published unless it has been approved by the State.

Exhibit E
Copyright / Ownership / Use of Data

C. Contractor agrees to deliver, in a form that can be used and reproduced by the State, any Works as defined in **Ownership of Intellectual Property and Materials**, developed in execution of this Agreement at completion of this Agreement. The Contractor shall deliver those copies to the State within ninety (90) calendar days of the completion of this Agreement.

D. The State shall have the right to order, at any time during the performance of this Agreement, or within three years from either acceptance of all items (other than data) to be delivered under this Agreement or termination of this Agreement, whichever is later, any Work and any data not called for in this Agreement but generated in performance of this Agreement. The Contractor shall promptly prepare and deliver that data as is ordered for actual costs of reproduction, including no more than 10% overhead. The Contractor shall exercise its best efforts to prepare and deliver such data as is ordered if the principal investigator is no longer associated with the Contractor. The Contractor shall be relieved of obligation to furnish data pertaining to an item obtained from a subcontractor upon the expiration of three years from the date the Contractor accepts such items.

When data, other than the Work as defined in Article I, Paragraph 2, **Ownership of Intellectual Property and Materials** is delivered pursuant to this section, payment shall be made, by equitable adjustment or otherwise, for converting the data into the prescribed form, reproducing it, or preparing it for delivery.

E. Contractor must request in writing and obtain written permission from the State to release to other parties data files, databases, or database systems except for those that are publicly available without restriction, provided by the State or prepared or collected under this Agreement within thirty (30) calendar days before the release of the data files, databases, or database systems.

V. Conditions Applicable to Independent Research

1. "Independent research project" is defined as research, articles, reports, and materials that is not necessary for performance of this Agreement, produced by Contractor and Contractor's faculty, students, or staff using data provided by the State or collected or prepared under this Agreement. Independent research projects shall not have been produced in performance of this Agreement, nor during time invoiced to the Department, nor paid for, under this Agreement.

2. Contractor shall request prior written permission from the State to use confidential information in data from State databases or collected or prepared under this Agreement according to the requirements of the source database or the appropriate human subject review board. "Confidential information" means any information containing patient identifiers, including but not limited to, name, address, telephone number, social security number, medical identification number, and drivers license number.

3. The Contractor shall include in all data/research reports or publications (a) a disclaimer that credits any analysis, interpretations, or conclusions reached to the author(s) and not to the State, and (b) a statement on the biases in the data known to affect the report findings. Independent research projects shall not contain the publication credit in **Publication Credit**.

Exhibit E
Copyright / Ownership / Use of Data

4. Contractor shall supply the State with a copy of the final product three (3) weeks prior to the date of submission for publication, and a copy of the final publication for independent research project articles, reports or materials intended for publication. The State shall not release the articles, reports or materials or comment publicly prior to their scheduled release.

5. Contractor must request in writing and obtain written permission from the State to release to other parties data files, databases, or database systems except for those that are publicly available without restriction, provided by the State, or prepared or collected under this Agreement within thirty (30) calendar days before the release of the data files, databases, or database systems. Contractor can use and release individual data elements without prior approval from the State.

VI. Publication Credit

The Contractor shall include a statement giving credit for support by the State on the title page of deliverable public reports or publications regarding any work performed with funds provided under this Agreement, such as:

" This project was supported by funds received from the State of California, California Environmental Protection Agency, _____." In addition to the requirements **Conditions Applicable to Reports/Publications Deliverable to the State**, the Contractor must also include this statement on any curriculum, educational materials, programs, program documentation, videotapes, and/or other audio-visual materials (Works) resulting from this Agreement.

VII. Satisfactory Deliverables

Contractors must provide the State with deliverables that are of the highest quality, including the use of highest quality concepts developed under this Agreement. If satisfactory deliverables are not received, the State shall not approve for payment subsequent invoices under the terms of the Agreement until the State receives satisfactory deliverables. Deliverables must not contain confidential information in violation of state or federal law or the requirements of the appropriate human subjects review boards. "Confidential information" means any information containing patient identifiers, including but not limited to: name, address, telephone number, social security number, medical identification number, driver's license number.

Exhibit F
California Environmental Protection Agency (Cal/EPA)
External Scientific Peer Review Guidelines
Gerald W. Bowes, Ph.D.

November 2006

Background

In 1997, the Governor signed into law Senate Bill 1320 (Sher 1997). The language is now incorporated into Health and Safety Code Section 57004. The statute requires the six Cal/EPA organizations* to submit for external scientific peer review all proposed rules that have a scientific basis or components.

The guidance described herein was developed to implement the statute requirement for the California State Water Resources Control Board and nine Regional Water Quality Control Boards. This original Water Board focus in no way limits its use by all Cal/EPA organizations, for which it is now intended. In future updates, references and examples relating to media topics beyond water quality will be included if considered useful.

These guidelines also shall apply to all subjects chosen for external peer review, whether or not they are subject to the statute requirement, as described below. Reviewer candidates for all reviews must meet the same no conflict of interest provisions.

The Statute Requirement for External Scientific Peer Review

The language from Health and Safety Code Section 57004 that relates to external scientific peer review is provided here as Attachment A. It defines the essence of our challenge, and describes the responsibilities of both the organization requesting the review, and the reviewers. As noted, the requirement refers to all proposed rules that have a "scientific basis" or "scientific portions," and these phrases are defined in the code. The "agency" referred to is Cal/EPA. The statute notes that no Cal/EPA organization shall take any action to adopt the final version of a rule unless several conditions are met. One of these is that **"The board, department or office submits the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation."**

With respect to proposals involving water quality objectives, we interpret this to include the soundness of the scientific basis of the objectives themselves, and the context in which they are to be implemented.

The peer review process described in these guidelines includes independent identification of external peer reviewer candidates by an outside party. This is achieved through a contractual arrangement Cal/EPA has with the University of California, Berkeley. All candidates must complete and sign a Conflict of Interest (COI) Disclosure form that is reviewed by an independent entity identified by Cal/EPA. Only approved candidates can serve as external peer reviewers.

* (1) Air Resources Board; (2) Department of Pesticide Regulation; (3) Department of Toxic Substances Control; (4) Integrated Waste Management Board; (5) Office of Environmental Health Hazard Assessment; and (6) State Water Resources Control Board and nine Regional Water Quality Control Boards.

Exhibit F
California Environmental Protection Agency (Cal/EPA)
External Scientific Peer Review Guidelines
Gerald W. Bowes, Ph.D.

November 2006

Do all Proposed Rules or Amendments with Scientific Components Require Scientific Peer Review?

Sometimes the answer is No, peer review is not needed, or, at least, not for all of it. A Cal/EPA document provides some assistance for making this decision. It is titled, *Unified California Environmental Protection Agency Policy and Guiding Principles for External Scientific Peer Review*, March 13, 1998 (Cal/EPA Guiding Principles). It notes that there are several circumstances where work products do not require peer review under SB 1320 (Health and Safety Code Section 57004), including the following:

> *A particular work product that has been peer reviewed with a known record by a recognized expert or expert body. Additional review is not required if a new application of an adequately peer reviewed work product does not depart significantly from its scientific approach. These types of work products would include standards developed by the U.S. EPA, which Cal/EPA adopts. These U.S. EPA standards are presumed to have been sufficiently peer reviewed unless additional peer review is required by law.*

The "USEPA standards" are those that appear in a final (not draft) EPA document, which is understood to have met EPA adoption requirements. That is, the draft document was sent out for scientific peer review, and the final document satisfactorily addressed reviewers' comments, as EPA considered appropriate and necessary.

Note the caveat to this and other potential exceptions described in the "Implementing Language" section below.

Consideration Should be Given to Whether the Scientific Basis for a Specific Rule, Major Scientific Initiative, or Method not Subject to Health and Safety Code Section 57004 Should be Submitted for External Scientific Peer Review

The Cal/EPA Guiding Principles document identifies such categories of work products (pp 6-7), as described below. The distinguishing feature of these is that they address important scientific topics which would have statewide significance. Examples are as follows:

1) *Products that Address Emerging or Controversial Issues, Have Significant Cross-Media Implications, or Establish a Significant Precedent*
   e.g., Application of new scientific findings in hazardous waste classification.
   e.g., Risk assessment methods, development, and findings. (For example, impacts concerning children or new environmental chemical fate transport models that substantially modify risk outcomes.)

2) *Scientific Products that Support Regulations, Standards, or Rules*
   e.g., Critical technical guidance documents for the regulated community.

3) *New Decision Criteria, Analytical Tools, or Models of Significance or Changes in Assessment Methodologies to be Used Routinely in Risk Assessment*
e.g., Significant new or revised models and other techniques designed to predict exposure, simulate transport, etc.
e.g., Changes or innovations in analytical measurement techniques for pollutants.

Work Products Not Requiring Peer Review

The Cal/EPA Guiding Principles document referred to above notes that there are several circumstances where peer review is not required under Health and Safety Code Section 57004. These are in addition to the EPA standards example given in the section above titled, *Do All Proposed Rules . . . .* Peer review is not required for permits, variances, enforcement actions, and similar types of activities, unless they are accomplished through rulemaking.

Implementing Language Must Be Submitted For External Review

The context in which the "science" is to be applied must be understood by the reviewer. With respect to water quality objectives, their implementation in a proposed rule is an integral part of the rule's scientific basis. This use of the objectives must be submitted for external review even if the objectives themselves had previously been accepted as scientifically sound.

For example, proposed numerical water quality objectives for recreational shellfish harvesting waters may be identical to those recommended by the California Department of Health Services and the U.S. Food and Drug Administration. Peer review could be assumed to be not needed. However, these numbers are integral to a specific sampling strategy and statistical context and, if any of the associated parameters are different in the regulatory action proposed for adoption a peer review must be performed.

For a Water Board Basin Plan Amendment for example, the material to be reviewed must include the amendment language. Where some uncertainty exists, staff should contact me in writing. I may seek input from legal counsel, before responding in writing for the project record.

The Decision to Request External Reviewers: Who is Responsible?

Management in the Cal/EPA organizations is responsible for deciding whether or not a proposal should be submitted for external scientific peer review. Management must be familiar with and have approved the detail of the request letter and its attachments, described below. One of the attachments highlights the essential scientific topics to be reviewed and commented upon.

Another reason for ensuring that the proposal is a solid product with committed organization support is that a considerable effort is directed to identifying willing and conflict-of-interest free candidates who are noted experts in their fields. Candidates are drawn from academic institutions across the country.

The external review is not a time for seeking technical advice. The process is not a collaboration. The proposed rule sent out for external review is draft final and based on sound scientific

principles, in the best professional judgment of management and staff. The proposal must be clearly expressed and based on defensible logic.

Staff are encouraged to find colleagues who are preparing, or who have prepared, similar requests to gain from an exchange of ideas. Also, other entities within the organization making the request will have a role in review of the proposal in the path leading to adoption. Inform them, including legal counsel, about the intended proposal and solicit comment as necessary.

If a decision is made that peer review is not necessary, that conclusion must stand up to future challenge which could stop the proposed action in its tracks. A successful challenge would result in initiation of the peer review process. All of this could add months to the original adoption schedule. The decision to go ahead with peer review, or not, should be well thought out.

The external scientific peer review should take place and changes made which staff consider necessary, before documents are sent out for public comment. Demanding schedules sometimes require both reviews to take place simultaneously. Avoid this if possible.

Signing the Request for External Reviewers

Within the State and Regional Water Boards, the level of the person signing the request has been left to the discretion of the respective organizations. Some prefer that the Executive Officer or Assistant Executive Officer sign. At the minimum, the request should be signed by the second supervisory level or above.

The request includes a clear and detailed description of the scientific basis of the proposal, and it highlights the individual topics that later will be the focus of each reviewer's attention. Those topics, the comments on them by noted experts, and subsequent Cal/EPA organization response all will become part of the public record and the administrative record which is the legal basis for a Cal/EPA organization action.

This signoff by management is the most effective and consistent way of ensuring that staff and management are equally familiar with the details of the request. The reference to consistency is based in part on an observed flux in staff in the organizations, which has shown that the peer review mandate and the details for carrying it out continues to be a new learning experience for many. The need for management signature is based also on the assumption that management is familiar with the peer review process and will provide guidance to staff, as necessary.

Submitting the Request for External Reviewers

The request is initiated by writing a letter to me with the information listed below. It should be sent in **draft** email form, with three attachments.

This draft can be sent by staff after management review. The letter itself will:

(a) describe the purpose of the request, noting that if the proposal for review is intended for eventual adoption, the proposed adoption date will be identified;

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(b) indicate the date the documents will be ready for review, and your preferred period of review (I suggest 30 days). Please be as accurate as you can about document availability. Often, reviewers agree to do the work within a certain time frame;
(c) emphasize the importance of keeping to the review schedule. (As noted above, the external scientific peer review should take place before the public comment period.)
(d) recommend the kinds of expertise staff believes is appropriate for the review (Highlight the expertise considered essential); **Recommendations for reviewers are not permitted.**
(e) provide the name, phone number, and e-mail address of the staff contact for the project.

The three attachments will provide the information described below:

Attachment 1: A plain English summary of the proposal, which is intended for future organization action. This could be done on one page.

Attachment 2: The scientific issues you want the reviewers to address and comment on.

The following two paragraphs will precede the list of scientific issues:

"The statute mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

We request that you make this determination for each of the following issues that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review."

The following paragraph must be added here if a proposed rule is not the subject of review: **"For those work products which are not proposed rules, reviewers must measure the quality of the product with respect to the same exacting standard as if it was subject to Health and Safety Code Section 57004 requirements."**

An explanatory paragraph or two must be provided to the reviewers for each issue you are presenting to them. This will make it much easier for reviewers to know what your challenge is, and how you have addressed it.

The last scientific issue should be followed by this statement to ensure the reviewer is given an opportunity to comment on the proposed Board action as a whole:

"The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the following questions.

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(a) In reading the staff technical reports and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.

(b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statute requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have an opportunity to comment on all aspects of the scientific basis of the proposed Board action. At the same time, reviewers also should recognize that the Board has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed."

An excellent example of the suggested format is attached (Attachment B to this guidance). It describes a proposed site-specific objective. Note that questions are not asked. Independent scientific peer review is not a vehicle for seeking technical advice.

Attachment 3: A listing of people who have participated in the development of the proposal. The intent here is to identify academicians and other researchers from any of the California university systems, public or private, and outside them, that have participated in any stage of project development. The peer review statute forbids any such participant from taking part in the review. So we want to know who they are: **"No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule."**

How Long will it Take to Have Reviewers Identified and Cleared for the Review Assignment?

The period of time from my receipt of the final request to my contacting you later with names of approved reviewers, can range up to two months. This covers the period for finding candidates by the University of California (UC) Project Director; completing the COI Disclosure form and review by an independent entity. The UC Project Director and I receive a letter from the reviewing authority indicating whether or not the candidates have passed the test. If a candidate has not been approved, a search for a replacement with comparable expertise is initiated. On these occasions, the two-month period could be exceeded.

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What Happens After the Draft Request is Submitted?

I will review the draft to ensure that all the required topics are covered and that they are clearly presented to minimize questions of clarification by the UC Project Director, potential reviewer candidates, and selected reviewers once the review is underway. This reading of the draft will be done quickly. After the review, I will contact the person who sent the request, suggest changes if any are thought to be necessary, and ask that the final request (letter and three attachments) be sent to me electronically with a signed, hard copy in the mail to follow. Then I will send the electronic copy to the UC Project Director. This person is not identified in this guidance to emphasize the importance of the independence afforded the University in selecting reviewers for Cal/EPA following strict conflict-of-interest considerations.

The UC Project Director sends the same request information to potential reviewer candidates. This opens a communication to determine if the candidates are interested and qualified. Once suitable candidates are identified, they are asked to complete and sign the COI Disclosure form.

My Response Letter to You

When candidates are approved as reviewers, I will write a letter to the Cal/EPA organization representative who requested the external reviewers. The letter will identify reviewers and provide contact and biographical information. An example of this letter is included here as Attachment C. From this point forward, all subsequent communications will be directly between the organization requesting the review, and the reviewers.

My letter will tell you to contact reviewers **immediately**, and let them know you have been informed that they have been approved as reviewers. The letter also will tell you to let them know your latest schedule for sending the review materials to them. Keep them current on changes to this schedule. Their acceptance of the assignment often is conditional upon the original schedule, so you will have to determine if changes are acceptable to them. Keep me informed of significant schedule changes as I am sometimes contacted by the University or the reviewers when delays occur.

Providing Guidance to Reviewers

Your second contact with reviewers will take place when you send them the material to be reviewed. A cover letter and attachments providing guidance to the reviewers must accompany this material. The three attachments originally sent with the letter of request for reviewers must be included with this cover letter. The reviewers must clearly understand that the focus of the review will be the topics identified in Attachment 2. Reviewers should have been sent this information by the UC Project Director during the initial search for candidates. Regardless, it now should be sent directly from the Cal/EPA organization to provide direction and context for the review.

Reviewers' Responsibility

From Health and Safety Code Section 57004:

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"The external scientific peer review entity, within the timeframe agreed upon by the board, department, or office and the external scientific peer review entity, prepares a written report that contains an evaluation of the scientific basis of the proposed rule. If the external scientific peer review entity finds that the board, department, or office has failed to demonstrate that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices, the report shall state that finding, and the reasons explaining the finding, within the agreed-upon timeframe."

Response to Reviewers: Cal/EPA Organization Responsibility, and Flexibility in Response

From Health and Safety Code Section 57004:

"The board, department, or office may accept the finding of the external scientific peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the Board, department, or office disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices."

Such a determination and supporting rationale must be brought to the attention of the Board, Department, or Office at the time the Rule is proposed for adoption. In adopting the proposed Rule, the Board, Department, or Office would be concurring with staff's rationale.

Additional Information: Questions and Responses

1. **How many reviewers are assigned to a project?**

   The complexity of the proposal and essential expertise identified for its review will provide a basis for the number of reviewers identified for a proposal. The number assigned, and the expertise, is determined by the UC Project Director after careful consideration of the information provided in the request letter and its attachments. For Water Board proposals, the number of reviewers has ranged from one to eight.

2. **Do reviewers interact with one another as a committee?**

   Normally, reviewers act independently and are not organized as committees. This has proved to be the most efficient way of getting the Water Boards the information they need as they move forward to consider adoption of a science-based regulation. Committees can be formed, but the potential need for members to interact would extend the suggested 30-day review period.

3. **Does a Cal/EPA organization have any right to reject a reviewer if it feels that person is not appropriate for the assignment?**

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As noted in (1) above, the University Project Director identifies reviewer candidates based on the information provided in the letter of request for reviewers. This includes a description of recommended reviewer expertise. If the requesting organization feels that essential expertise is not represented by the identified reviewers, then I should be informed in writing with the reasons for this conclusion. I will forward this statement to the University Project Director and, if justification is sound, an additional reviewer will be found for the assignment.

4. **Are discussions between staff and reviewers permissible?**

No. There is one exception - the reviewers' need for clarification of certain aspects of the documents being reviewed, where this need has been expressed. Clarification questions and responses to them must be transmitted in writing. These communications will become part of the administrative record. Independent peer review is characterized by no interactions, or a limited number of them. The organization requesting independent review should be careful that staff-reviewer communications do not become a collaboration, or are perceived by others to have become so. The reviewers are not technical advisors.

5. **If a proposal has been revised significantly, and a Cal/EPA organization wants it reviewed again, can the organization send it back to the same reviewers for another look?**

No. This could unintentionally lead to collaboration, or the appearance of such, which must be avoided. Write me a letter stating the nature of the changes and identify the original reviewers. Add anything else that is relevant to the revision. I will contact the UC Project Director and transmit the justification for the request. The Project Director will decide who should review the revised documents. If different from the original reviewers, each would have to complete a COI Disclosure form. I will contact you after this decision has been made.

6. **Do we need to respond to reviewers?**

As a matter of courtesy, the Cal/EPA organization should acknowledge receipt of the comments and thank the reviewers for taking time to review the scientific basis of the proposed rule or other work product.

Reviewers also will be interested to know how the organization responded to their comments. As required by statute, the Cal/EPA organization can agree with critical comments, and make adjustments to meet this criticism; or it can disagree, but it is required to state why for each point of contention, the organization's proposal is based on sound scientific principles.

If the organization provides this follow-up information to the reviewers, I recommend that it be done when the proposal has been revised as necessary, and it is ready to be sent out for public comment. This courtesy communication to reviewers is not meant to establish a dialogue or collaboration that could influence subsequent Board action.

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7. **If we are asked for a copy of reviewers' comments, at what point in the process should they be released?**

   Legal counsel advises that reviewers' comments are a matter of public record at the time they are received by the Cal/EPA organization, and should be given to a requestor at that time.

   Cal/EPA staff may feel more comfortable by first preparing responses to the comments and adjusting the proposed rule or work product as necessary prior to release for public comment, before releasing the comments. Staff may suggest this as an alternative to a requestor. However, if this person wants them upon receipt by the Cal/EPA organization, the review comments must be provided at that time.

8. **If a reviewer sends an invoice with a copy of the review to the Cal/EPA organization requesting the review, what should be done with the invoice?**

   The Cal/EPA organization should keep the review, but return the invoice to the reviewer.

   All reviewers previously have been instructed that upon completion of the assignment, they shall send one full set copy of the peer review directly to the Cal/EPA requesting organization and one full set copy to the UC Project Director. The reviewers shall **only** send their invoices directly to the UC Project Director for review/approval, and not to the Cal/EPA organizations. The UC Project Director will authorize payment for completed reviews.

9. **Should there be any contact between Cal/EPA organizations requesting a review and the UC Project Director, at any time?**

   No. This person is a neutral third party whose responsibility it is to identify reviewer candidates based on material prepared by a Cal/EPA organization. The strength of our peer review process is the independence afforded this individual. This keeps Cal/EPA organizations free of any perception that they might influence selection of reviewer candidates for the current proposal and those in the future.

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