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

BCO #6586

AGREEMENT NUMBER
11-135-240 CALEPA 11-021
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 SWRCB 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: Upon DGS Approval through June 30, 2016

3. The maximum amount of this Agreement $ 1,969,797
One Million Nine Hundred Sixty Nine Thousand Seven Hundred Ninety Seven 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	7 Pages
Exhibit A, Attachment 1, Reviewer Background / Conflict Of Interest Worksheets	15 Pages
Exhibit A, Attachment 2, Peer Review Guidelines & Sample Correspondence	22 Pages
Exhibit A, Attachment 3, Supplement to Peer Review Guidelines	3 Pages
Exhibit B - Budget Detail & Payment Provisions	5 Pages
Exhibit B, Attachments 1 – 5, Budgets by Fiscal Year (FYs 11/12 – FY 15/16)	5 Pages
Exhibit C* - General Terms and Conditions	GIA 610
Exhibit D - Additional Provisions	4 Pages
Exhibit E - Federal Provisions Copyright / Ownership / Use of Data	5 Pages

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)*: 12-12-11

PRINTED NAME AND TITLE OF PERSON SIGNING
Brian Donohue, J.D., Business Contract Administrator

ADDRESS
Business Contracts Office, 412 O'Brien Hall, MC 5620
University of California Berkeley, Berkeley, CA 94720-5620

STATE OF CALIFORNIA

AGENCY NAME
California Environmental Protection Agency

BY *(Authorized Signature)* — DATE SIGNED *(Do not type)*: 12/29/11

PRINTED NAME AND TITLE OF PERSON SIGNING
Eric Jarvis, Assistant Secretary for Fiscal and Administrative Programs

ADDRESS
1001 I Street, Sacramento, CA 95814

California Department of General Services Use Only

ECH

APPROVED
JAN 12 2012
DEPT OF GENERAL SERVICES

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California Air Resources Board – Contract Number: 11-825

Socorro Watkins, Branch Chief
Business Management Branch

12/15/11
Date

Department of Pesticide Regulation – Contract Number: 11-C0101

Anise Severns, Branch Chief
Fiscal Services and Business Operations Branch

12/15/11
Date

Department of Toxic Substances Control – Contract Number: 11-T1062

Sandra Poindexter, Branch Chief
Contracts & Business Management Branch

12/15/11
Date

Office of Environmental Health Hazard Assessment – Contract Number: 11-E0017

Margie Leary, Deputy Director
Administrative Support Services

12/14/11
Date

State Water Resources Control Board – Contract Number: 11-135-240

David Brady, Manager Procurement and Contracts
Division of Administrative Services

12/15/11
Date

Exhibit A
Scope of Work

1. Service Overview

The Regents of the University of California, Berkeley, (Contractor) agree to provide the California Environmental Protection Agency and its Boards, Departments, and Offices (BDOs) as listed in Section 4 below (collectively referred to as "Cal/EPA"), with services for scientific peer review and other expert review (as described herein) upon request of Cal/EPA. The services may be provided by employees of the Contractor, or by subcontractors of the Contractor, as deemed appropriate by the Contractor, subject to the restrictions in Section 8.

The Contractor will provide a University Project Manager to serve as the point of contact for the Cal/EPA Project Manager. The University Project Manager is responsible for receiving and acting upon requests for services under this Agreement. Upon selection of a final University Project Manager position by the Contractor, the Contractor will notify Cal/EPA.

2. Project Representatives

A. The project representatives during the term of this agreement are the following. Either party may make changes to the information below by giving 10 days written notice to the other party. Said changes shall not require an amendment to this agreement.

A. Cal/EPA	The Regents of the UC, Berkeley
Dr. Gerald W. Bowes, Cal/EPA Project Manager 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. All inquiries shall be directed to:

B. Cal/EPA	The Regents of the UC, Berkeley
Attention: Dr. Gerald W. Bowes Office of Research, Planning and Performance State Water Resources Control Board 1001 I Street, 16th Floor Sacramento, CA 95814	Attention: Professor Garrison Sposito, University Principal Investigator Telephone: (510) 643-8297 Fax: (510) 643-2940 E-mail: mailto:gsposito@berkeley.edu Attention: Daniel T. McGrath, Ph.D., Acting University Project Manager.

Exhibit A
Scope of Work

Telephone: (916) 341-5567 Fax: (916) 341-5284 E-mail: gbowes@waterboards.ca.gov	Telephone: (510) 642-1385 Fax: (510) 642-0225 E-mail: dmcgrath@berkeley.edu The Regents of the UC, Berkeley Berkeley Institute of the Environment MC 1250 University of California, Berkeley Berkeley, CA 94720-1250

3. Background

There are several types of scientific/economic review for which services may be requested under this agreement, including mandated external scientific peer review, expert review of other technical work products, and review of model environmental curriculum. The following provides a brief context regarding the need for, and purpose of, each of these services.

Mandated External Scientific Peer Review
State law (Health and Safety Code Section 57004) sets minimum requirements for external scientific peer review. Notably, Health and Safety Code Section 57004 requires all Cal/EPA BDOs to submit for external scientific peer review the "scientific basis" and "scientific portions" of proposed rules, consistent with the statutory definition of these two terms. For external scientific peer reviews required by Health and Safety Code Section 57004, 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, must be submitted for peer review. The law specifies that an individual may not serve as an external scientific reviewer if that person participated in the development of the scientific basis or scientific portion of the proposed rule.

Expert Review of Other Technical Work Products
In addition to the work products for which external scientific peer review is statutorily required by Health and Safety Code section 57004 (as noted above), Cal/EPA may seek expert review, which may include peer review, of the scientific/economic basis and scientific/economic portions of other work products—for example, major and/or controversial new initiatives that are not otherwise subject to statutory peer review requirements—as it deems prudent.

Expert Review of Model Environmental Curriculum
State law (Public Resources Code Section 71300, et seq.) required the development of a model environmental curriculum. That curriculum was approved by the State Board of

Exhibit A
Scope of Work

Education; however, services maybe requested from time to time to address questions regarding the accuracy of discrete facts contained within the curriculum.

4. Cal/EPA Entities Participating in the Agreement

The Agreement shall provide for peer review services and other expert review services as outlined in this scope of work for any of the following Cal/EPA entities:

A. Office of the Secretary
B. Air Resources Board
C. Department of Pesticide Regulation
D. Department of Toxic Substances Control
E. Office of Environmental Health Hazard Assessment
F. State Water Resources Control Board (including the nine Regional Water Quality Control Boards)

5. Contractor Processing of Requests for Services

This Agreement provides for a process to identify scientific peer reviewers and other experts to review the types of work products noted above and outlined in more detail below. The selection of reviewer candidates under this Agreement shall be the sole responsibility of the Contractor, subject to the Cal/EPA conflict of interest criteria described below. Ensuring that the peer reviewers and other experts providing services under this Agreement are independent and free of actual and potential conflicts of interest is necessary for stakeholder confidence in the review process, and is therefore an integral function of this Agreement. To that end, Contractor agrees to the following procedures to ensure that the peer reviews and other expert reviews comply with applicable state law and Cal/EPA policy, and can be used by Cal/EPA for their intended purposes.

The Contractor shall ensure that each reviewer candidate completes and signs a Conflict of Interest (COI) Disclosure Form for submittal to the Cal/EPA Project Manager. The COI Form, which is based on a National Academy of Sciences model, is attached as Attachment 1. The use of any new or revised form shall be mutually agreed upon in writing by the University Principal Investigator and the Cal/EPA Secretary or designee who is closely familiar with this Agreement, but shall not require an amendment to this Agreement. The Cal/EPA Project Manager may contact potential reviewer candidates to follow up on any potential conflict of interest issues. The Cal/EPA Project Manager will notify the University Project Manager if any conflict of interest documents indicate a conflict of interest that would disqualify a candidate reviewer. The Contractor will exclude such individuals from the review process. Cal/EPA's determination regarding conflicts of interest shall be final.

In order to expedite the reviewer selection process, Cal/EPA will identify for the Contractor the names of potential reviewer candidates who participated in the development of the work

product being reviewed, so that these potential reviewer candidates may be removed from consideration.

Cal/EPA has developed policies entitled "Cal/EPA External Scientific Peer Review Guidelines," dated November 6, 2006, and "Supplement to Cal/EPA External Scientific Peer Review Guidelines," dated January 7, 2009. These policies apply to all scientific peer reviews required by Health and Safety Code section 57004. These policies contain directions and guidance for reviewers and Cal/EPA staff regarding procedures for requesting and conducting peer review, contacts between reviewers and Cal/EPA staff, confidentiality, and related matters. These policies are attached at Attachments 2 and 3. Cal/EPA may update these policies at its own discretion without amending this Agreement, but any material changes shall be mutually agreed upon in writing by the University Principal Investigator and the Cal/EPA Secretary or designee who is closely familiar with this Agreement. Contractor agrees that all peer reviewers providing scientific peer review services required by Health and Safety Code section 57004 under this Agreement shall follow the provisions of these policies that are applicable to reviewers. The actual procedures for scientific peer review and other expert review that are not required by Health and Safety Code section 57004 will be established on a project-by-project basis.

Consistent with the above procedures, the Cal/EPA Project Manager may provide the Contractor with procedural direction, including any necessary changes to the procedures during the course of the Agreement. The procedures may be modified to the extent necessary to reflect changes in state law or regulation, subject to 10 days prior notice to Contractor.

6. Contractor Responsibility for Scientific Peer Review and other Expert Review

Upon request by the Cal/EPA Project Manager, it is the Contractor's responsibility to identify reviewer candidates, and submit their names to the Cal/EPA Project Manager. The Cal/EPA Project Manager will initiate the reviewer selection process by providing the Contractor with a letter of request (or "charge") for candidate reviewers which specifies the nature of peer review or expert advice requested, including any applicable statutory requirements or policy guidance. The letter shall clearly identify associated background materials, the issues and areas of primary focus (interest), and the estimated level (duration) of effort anticipated for the review (See Exhibit A, Attachments 2 and 3).

Consistent with state law, for scientific peer reviews subject to Health and Safety Code Section 57004, the Cal/EPA Project Manager will submit to the Contractor, in a timely manner, the scientific portions and/or scientific basis of the 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 for review by the selected external peer reviewers. These materials will include all of the support materials specified in the original letter of request.

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The Contractor will communicate directly with selected reviewers regarding the peer review or other requests for expert review, and shall, if requested by the Cal/EPA Project Manager, serve as the facilitator if supplemental information is requested by a reviewer. The Contractor will ensure that the external peer reviewers prepare written reports that contain an evaluation of the scientific portions and/or scientific basis of the proposed rule for any peer reviews subject to Health and Safety Code Section 57004. For other reviews, the Contractor will ensure that reviewers provide an appropriate written document based on the nature of the review requested. In either instance (external peer reviews or other reviews) the Contractor will ensure that the reviewer submits with their review a complete list of the supplementary materials (e.g., additional documents, studies, models) provided by the requesting agency, as well as any other information that was examined in the course of their review. Depending upon the nature of the review, and the applicable legal requirements, the Contractor may be asked by the Cal/EPA Project Manager to provide for review of work products revised in response to reviewer requests for clarification as well as any document(s) articulating the staff response to requests for clarification.

The suggested 30-day review period can be changed at the mutual agreement of Cal/EPA and the reviewer. The Contractor will ensure that the reviewers send one full set copy of the peer review(s) or other report(s) directly to the Cal/EPA requesting organization and one full set copy to the University Project Manager along with an invoice.

7. **Contractor Responsibility for Curriculum Review**

Pursuant to Public Resources Section 71300, et seq., a model environmental curriculum was developed and approved by the State Board of Education (SBE). The curriculum was deemed accurate by the SBE; however, in furtherance of the intent of the Public Resources Code Section 71300 et seq., to provide a high quality and accurate curriculum to the public school students of California, the Contractor is to provide for the review of alleged factual inaccuracies in the model curriculum on behalf of the Cal/EPA Secretary.

The text of alleged inaccuracies (i.e., sentences and/or paragraphs) will be transmitted by Cal/EPA to the Contractor, along with pertinent information regarding the context of the review (e.g., the name and subject of the instructional material from which the text originates); the subject-matter expertise required (e.g., science, or history/social science); and a reasonable timeframe in which the review is to be completed. The Contractor will select a reviewer consistent with the reviewer selection process outlined in Sections 5 and 6 (above) and will ensure the reviewer provides a written response regarding the factual accuracy of the submitted text and recommend technical corrections, as appropriate. The written response is to be conveyed in the same manner, and under the same time guidelines as specified in Sections 5 and 6 (above).

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Scope of Work

8. Subcontractor Requirements

A. The Contractor may enter into subcontracts with qualified peer reviewers and other experts who have passed the Conflict of Interest review. The Contractor shall ensure that all subcontracts for review and other expert services include provision(s) requiring compliance with applicable terms and conditions specified in this Agreement.

B. Subcontracts (i.e., written agreements between the Contractor and a subcontractor) of $5,000 or more are subject to the prior review and written approval of Cal/EPA.

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

2. Cal/EPA 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.)

C. Contractor agrees that employees of any California state agency may not serve as subcontractors under this Agreement.

D. 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 for cause. 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.

E. Contractor shall consider the number of hours estimated for the peer review or other service by the Cal/EPA Project Manager in negotiating the terms of the subcontract. 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.

F. 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.

G. Contractor shall be given financial resources on an annual basis by Cal/EPA to fully operate this agreement with estimated salaries and benefits of assigned Contractor personnel being made by Cal/EPA at the beginning of each fiscal year of the Agreement. Contractor agrees to strictly follow the reporting requirements contained in Exhibit B.

H. Contractor is responsible for all performance requirements under this Agreement even though performance may be carried out through a subcontract.

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

J. 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 final payment and termination of (*Agreement Number*), 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."

K. The Contractor shall refer all matters relating to performance concerns of any vetted and selected reviewer to the Cal/EPA Project Manager.

University of California (UC)
Form for Obtaining Background Information
And Conflict of Interest Disclosure
For Activities Related to Government Regulation[1]

NAME:

ACADEMIC/PROFESSIONAL TITLE AND FULL ADDRESS:

TELEPHONE:
EMAIL:
FAX:
CURRENT EMPLOYER:

RELEVANT ACTIVITY TO WHICH THIS FORM RELATES: (List the activity relating to government regulation in which you have been asked by the University of California to participate -- e.g., name of Committee or Panel on which you have been asked to serve, or title of the proposed government standard or regulation you have been asked to review):

There are two parts to this form, Part I -- Background Information, and Part II -- Conflict of Interest Disclosure. Complete both parts, **sign** and **date** this form on the last page, and return the form to the Cal/EPA Project Manager, solely: Dr. Gerald W. Bowes, Manager, Cal/EPA Scientific Peer Review Program, 916.341.5567; GBowes@waterboards.ca.gov
Retain a copy for your records.

[1] This form was modeled closely on a background and conflict of interest disclosure form designed by the National Academies of Sciences (NAS) for use with respect to studies relating to government regulation. The University of California is grateful to the NAS for extending its permission to use the NAS form. This UC form is being put into provisional use in May, 2003, and may be subject to change. This form is to be used for members of scientific advisory panels that UC convenes at the request of the State and for UC-recommended experts whose reports and/or advice are to be provided to the state for official use in a government regulatory process. This form may be disclosable to the public under applicable state laws and regulations.

PART I -- BACKGROUND INFORMATION

Instructions

Please provide the information requested below regarding **relevant** organizational affiliations, government service, public statements and positions, research support, and additional information (if any). Information is "relevant" if it is related to -- and might reasonably be of interest to others concerning -- your knowledge, experience, and personal perspectives regarding the subject matter and issues to be addressed by the activity (e.g., committee membership or service as a scientific reviewer) for which this form is being prepared. **If some or all of the requested information is contained in a previously submitted copy of this form, you may if you prefer simply attach the previous copy, supplemented by additional responses or comments below as necessary.**

I. ORGANIZATIONAL AFFILIATIONS. Report your *relevant* business relationships (as an employee, owner, officer, director, consultant, etc.) and your relevant remunerated or volunteer non-business relationships (e.g., professional organizations, trade associations, public interest or civic groups, etc.).

report relevant relationships and affiliations here

II. GOVERNMENT SERVICE. Report your *relevant* service (full-time or part-time) with federal, state, or local government in the United States (including elected or appointed positions, employment, advisory board memberships, military service, etc.).

report relevant service here

continue here

III.EXTRAMURAL RESEARCH SUPPORT. Report *relevant* information for the past 5 years, including sources of funding, dates and approximate amounts for both public and private sources of research support.

Answer here

IV. PUBLIC STATEMENTS AND POSITIONS. List your *relevant* articles, testimony, speeches, etc., by date, title, and publication (if any) in which they appeared, or provide relevant representative examples if numerous. Provide a brief description of relevant positions of any organizations or groups with which you are closely identified or associated.

list relevant articles, testimony, speeches, et cetera here

V. ADDITIONAL INFORMATION. If there are *relevant* aspects of your background or present circumstances not addressed above that might reasonably be construed by others as affecting your judgment in matters within the assigned task of the committee or other activity in which you have been invited to participate, and therefore might constitute an actual or potential source of bias, please describe them briefly.

report additional information here

PART II -- CONFLICT OF INTEREST DISCLOSURE

Instructions

When the State of California requests the University of California's assistance in convening scientific advisory committees or recommending scientific experts to produce reports for the purpose of providing expert advice intended to be used by the State in formulating state laws or regulations, it is essential that the work of the participants in such activities not be compromised by any significant conflict of interest.

For this purpose, **the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.**

Except for those situations in which UC and/or the government agency requesting UC's assistance determines that a conflict of interest is unavoidable and publicly discloses the conflict of interest, no individual can be appointed to serve (or continue to serve) on a UC-convened scientific advisory committee or serve as a UC-recommended scientific expert or peer reviewer when the report(s) developed by such service are intended to be used by the State as part of the official process for developing government laws or regulations, if the individual has a conflict of interest that is relevant to the functions to be performed.

The term "conflict of interest" means something more than individual bias. There must be an *interest*, ordinarily financial, that could be directly affected by the work of the panel, committee or UC-recommended peer reviewer.

Conflict of interest requirements are *objective* and *prophylactic*. They are not an assessment of one's actual behavior or character, one's ability to act objectively despite the conflicting interest, or one's relative insensitivity to particular dollar amounts of specific assets because of one's personal wealth. Conflict of interest requirements are objective standards designed to eliminate certain specific, potentially compromising situations from arising, and thereby to protect the individual, the other members of the committee, the institution, and the public interest. The individual, the committee, and the institution should not be placed in a situation where others could reasonably question, and perhaps discount or dismiss, the work of the committee simply because of the existence of conflicting interests.

The term "conflict of interest" applies only to *current interests*. It does not apply to past interests that have expired, no longer exist, and cannot reasonably affect current behavior. Nor does it apply to possible interests that may arise in the future but do not currently exist, because such future interests are inherently speculative and uncertain. For example, a pending formal or informal application for a particular job is a current interest, but the mere possibility that one might apply for such a job in the future is not a current interest.

The term "conflict of interest" applies not only to the personal interests of the individual but also to the *interests of others* with whom the individual has substantial common financial

interests if these interests are relevant to the functions to be performed. Thus, in assessing an individual's potential conflicts of interest, consideration must be given not only to the interests of the individual but also to the interests of the individual's spouse and dependent children, the individual's employer, the individual's business partners, and others with whom the individual has substantial common financial interests. Consideration must also be given to the interests of those for whom one is acting in a fiduciary or similar capacity (e.g., being an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

This disclosure form is used for members of scientific advisory committees that UC convenes at the request of the state and for UC-recommended experts whose reports and/or advice are to be provided to a state agency or to the Legislature for official use in a government regulatory process. For such activities, *the focus of the conflict of interest inquiry is on the identification and assessment of any interests that may be directly affected by the use of such reports in the regulatory process*.

For example, if the UC-convened committee or the UC-recommended reviewer were conducting a study of proposed modifications in the government regulation of a particular application of biotechnology, the focus of the conflict of interest inquiry would be on the identification and assessment of any interests that would be directly affected by that regulatory process if the report were to provide the basis for regulatory action or inaction. The concern is that if an individual (or others with whom the individual has substantial common financial interests) has specific interests that could be directly affected by the regulatory process, the individual's objectivity could be impaired.

Such interests could include an individual's significant stock holdings in a potentially affected biotechnology company or being an officer, director, or employee of the company. Serving as a consultant to the company could constitute such an interest if the consulting relationship with the company could be directly affected or is directly related to the subject matter of the regulatory process.

An individual's other possible interests might include, for example, relevant patents and other forms of intellectual property, serving as an expert witness in litigation directly related to the subject matter of the regulatory process, or receiving research funding from a party that would be directly affected by the regulatory process if the research funding could be directly affected or is directly related to the subject matter of the regulatory process and the right to independently conduct and publish the results of this research is limited by the sponsor. Consideration would also need to be given to the interests of others with whom the individual has substantial common financial interests -- particularly spouses, employers, clients, and business or research partners.

The following questions are designed to elicit information from you concerning possible conflicts of interest that are relevant to the functions to be performed by the particular committee on which you have been invited to serve or to the function you have been asked to serve as a scientific peer reviewer.

1. EMPLOYMENT. (a) If the reports resulting from this activity (e.g., committee service or service as a scientific peer reviewer) were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports –

(i) if you are employed or self-employed, could your current employment or self-employment (or the current employment or self-employment of your spouse or dependent children) be directly affected?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(ii) to the best of your knowledge, could any financial interests of your (or your spouse's or dependent children's) employer or, if self- employed, your (or your spouse's or dependent children's) clients and/or business partners be directly affected?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(iii) if you are an officer, director or trustee of any corporation or other legal entity, could the financial interests of that corporation or legal entity be directly affected?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(iv) if you are a consultant (whether full-time or part-time), could there be a direct effect on any of your current consulting relationships?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(v) regardless of the potential effect on the consulting relationship, do you have any cur rent or continuing consulting relationships (including, for example, commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, serving as an expert witness in litigation, or providing services in exchange for honorariums and travel expense reimbursements) that are directly related to the subject matter of the possible government regulatory action or inaction?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) If you are or have ever been a government employee (either civilian or military), to the best of your knowledge are there any federal or state conflict of interest restrictions that may be applicable to your service in connection with this committee activity?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(c) If you are a government employee, are you currently employed by a state or federal agency that is sponsoring this project? If you are not a government employee, are you an employee of any other sponsor (e.g., a private foundation) of this project?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

2. INVESTMENT INTERESTS. Taking into account stocks, bonds, and other financial instruments and investments including partnerships (but excluding broadly diversified mutual funds and any investment or financial interest valued at less than $10,000), if the reports resulting from this activity (e.g., committee service or service as a scientific peer reviewer) were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(a) do you or your spouse or dependent children own directly or indirectly (e.g., through a trust or an individual account in a pension or profit-sharing plan) any stocks, bonds or other financial instruments or investments that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) do you have any other significant financial investments or interests such as commercial business interests (e.g., sole proprietorships), investment interests (e.g., stock options), or personal investment relationships (e.g., involving parents or grandchildren) that could be affected, either directly or by a direct effect on the business enterprise or activities underlying the investments?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if

necessary).

3. PROPERTY INTERESTS. Taking into account real estate and other tangible property interests, as well as intellectual property (patents, copyrights, etc.) interests, if the reports resulting from this activity (e.g., committee service or service as a scientific peer reviewer) were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(a) do you or your spouse or dependent children own directly or indirectly any such property interests that could be directly affected?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly descri be the circumstances here (continuing on the last page of the form if necessary).

(b) to the best of your knowledge, do any others with whom you have substantial common financial interests (e.g., employer, business partners, etc.) own directly or indirectly any such property interests that could be directly affected?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

4. RESEARCH FUNDING AND OTHER INTERESTS. (a) Taking into account your research funding and other research support (e.g., equipment, facilities, industry partnerships, research assistants and other research personnel, etc.), if the reports resulting from this activity (e.g., committee service or service as a scientific peer reviewer) were to provide the basis for government regulatory action or inaction with respect to the matters addressed in the reports --

(i) could the research funding and support for you or your close research colleagues and collaborators be directly affected, or

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(ii) if you have any research agreements for current or continuing research funding or support from any party whose financial interests could be directly affected, and such funding or support is directly related to the subject matter of the regulatory process, do such agreements significantly limit your ability to independently conduct and publish the results of your research (other than for reasonable delays in publication in order to file patent applications)?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(b) Is the central purpose of the project for which this disclosure form is being prepared a critical review and evaluation of your own work or that of your employer?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if

necessary).

(c) Do you have any existing professional obligations (e.g., as an officer of a scientific or engineering society) that effectively require you to publicly defend a previously established position on an issue that is relevant to the functions to be performed in this activity (e.g., committee service or service as a scientific peer reviewer)

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(d) To the best of your knowledge, will your participation in this activity (e.g., committee service or service as a scientific peer reviewer) enable you to obtain access to a competitor's or potential competitor's confidential proprietary information?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(e) Could your participation in this activity (e.g., committee service or service as a scientific peer reviewer) create a specific financial or commercial competitive advantage for you or others with whom you have substantial common financial interests?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if

necessary).

(f) If the activity (e.g., committee service or service as a scientific peer reviewer) for which this form is being prepared involves reviews of specific applications and proposals for contract, grant, fellowship, etc. awards to be made by sponsors, do you or others with whom you have substantial common financial interests, or a familial or substantial professional relationship, have an interest in receiving or being considered for awards that are currently the subject of the review being conducted?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(g) If the activity (e.g., committee service or service as a scientific peer reviewer) for which this form is being prepared involves developing requests for proposals, work statements, and/or specifications, etc., are you interested in seeking an award under the program for which the committee on which you have been invited to serve is developing the request for proposals, work statement, and/or specifications -- or, are you employed in any capacity by, or do you have a financial interest in or other economic relationship with, any person or organization that to the best of your knowledge is interested in seeking an award under this program?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(h) Have you participated in the development of the scientific basis or scientific portion of the proposal or document(s) to be reviewed?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

(i) Do you have any economic conflict of interest with regard to the outcome of your comments or recommendations on the proposal or document(s) to be reviewed?

☐ **YES** ☐ **NO** ☐ **NOT APPLICABLE**

If "Yes," briefly describe the circumstances here (continuing on the last page of the form if necessary).

FURTHER EXPLANATION OF "YES" RESPONSES:

provide further explanation here

During your period of service in connection with the activity for which this form is being completed, any changes in the information reported, or any new information which needs to be reported, should be reported promptly by written or electronic communication to the responsible UC administrator

_____ _____

YOUR SIGNATURE (PRINT NAME) DATE

Reviewed by: _____ _____

DATE

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.

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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.

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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.

(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?**

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.

Gerald W. Bowes, Ph.D.
Staff Toxicologist (Sup.)
Manager, Toxicology and Peer Review Section
Division of Water Quality
State Water Resources Control Board
1001 I Street
Sacramento, CA 95814
Telephone: (916) 341-5567
FAX: (916) 341-5463
Email: gbowes@waterboards.ca.gov

Health and Safety Code

§57004. Scientific Peer Review

(a) For purposes of this section, the following terms have the following meanings:
  (1) "Rule" means either of the following:
    (A) A regulation, as defined in Section 11342.600 of the Government Code.
    (B) A policy adopted by the State Water Resources Control Board pursuant to the Porter-Cologne Water Quality Control Act (Division 7 (commencing with Section 13000) of the Water Code) that has the effect of a regulation and that is adopted in order to implement or make effective a statute.
  (2) "Scientific basis" and "scientific portions" mean those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

(b) The agency, or a board, department, or office within the agency, shall enter into an agreement with the National Academy of Sciences, the University of California, the California State University, or any similar scientific institution of higher learning, any combination of those entities, or with a scientist or group of scientists of comparable stature and qualifications that is recommended by the President of the University of California, to conduct an external scientific peer review of the scientific basis for any rule proposed for adoption by any board, department, or office within the agency. The scientific basis or scientific portion of a rule adopted pursuant to Chapter 6.6 (commencing with Section 25249.5) of Division 20 or Chapter 3.5 (commencing with Section 39650) of Division 26 shall be deemed to have complied with this section if it complies with the peer review processes established pursuant to these statutes.

(c) 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.

(d) No board, department, or office within the agency shall take any action to adopt the final version of a rule unless all of the following conditions are met:
  (1) 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.
  (2) 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. 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.

(e) The requirements of this section do not apply to any emergency regulation adopted pursuant to subdivision (b) of Section 11346.1 of the Government Code.

(f) Nothing in this section shall be interpreted to, in any way, limit the authority of a board, department, or office within the agency to adopt a rule pursuant to the requirements of the statute that authorizes or requires the adoption of the rule.

California Regional Water Quality Control Board

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The Regents of the University of California, Berkeley
SWRCB Contract # 11-135-240, EXHIBIT A, ATTACHMENT 2

To: Dr. Gerald W. Bowes

From: Renee Purdy DeShazo
Staff Environmental Scientist

Re: Request for External Peer Review of Proposed Basin Plan Amendment to Adopt Site-Specific Ammonia Objectives

Date: April 15, 2004

The Los Angeles Regional Water Quality Control Board (LA Regional Board) requests by transmittal of this memo that State Board identify and assign reviewers to provide external peer review of a proposed Basin Plan amendment per the requirements of Health and Safety Code section 57004.

The proposed amendment would incorporate site-specific ammonia objectives (SSOs) for select inland fresh waters, including various reaches of the Santa Clara River, San Gabriel River and its tributaries, and Los Angeles River and its tributaries. The proposed amendment would change the current 30-day average (i.e. chronic) ammonia objective set to protect aquatic organisms for this subset of inland fresh waters. (The current Basin Plan objective is based on US EPA's most recent recommended federal CWA section 304(a) criteria for ammonia, published in 1999.) The goal of this amendment is to take into account site-specific conditions that may alter the toxicity of ammonia to aquatic life. The proposed site-specific objectives are based on water effect ratios (WERs), which take into account the difference in ammonia toxicity observed in local water bodies as compared to that observed in laboratory water.

The Los Angeles Regional Board at its regularly scheduled meeting on August 5, 2004 will consider the proposed amendment. The staff report and supporting technical reports will be ready for review by May 3, 2004. Given the importance of this amendment, we request that the reviewers provide comments within 30 days of receipt of the staff report and supporting documents.

We recommend that State Board solicit reviewers with expertise in toxicity and water chemistry and a familiarity with standards development and, specifically, methods for deriving site-specific objectives.

Additional background information for the proposed basin plan amendment is provided in Attachment 1. Scientific issues to be addressed by peer reviewers are listed in Attachment 2. Individuals involved in development of the proposed amendment are identified in Attachment 3.

The staff contact for this amendment is Renee DeShazo, who can be reached at (213) 576-6783 or via e-mail at rdeshazo@rb4.swrcb.ca.gov. Please feel free to call me if you have any questions about this request, and thank you for your assistance.

Proposed Ammonia Site-Specific Objectives for the Los Angeles, Santa Clara and San Gabriel Rivers and their Tributaries

Summary of Proposed Action

I. Summary

The Regional Board staff proposes an amendment to the Basin Plan to incorporate site-specific ammonia objectives (SSOs) for select inland fresh waters, including various reaches of the Santa Clara River, San Gabriel River and its tributaries, and Los Angeles River and its tributaries. The proposed amendment would change the current 30-day average (i.e. chronic) ammonia objectives set to protect aquatic organisms for this subset of inland fresh waters. (Current Basin Plan objectives are based on US EPA's most recent recommended federal CWA section 304(a) criteria for ammonia, published in 1999.) The goal of this amendment is to take into account site-specific conditions that may alter the toxicity of ammonia to aquatic life. The proposed site-specific objectives are based on water effect ratios (WERs), which take into account the difference in ammonia toxicity observed in local water bodies as compared to that observed in laboratory water.

II. Rationale

In 1999, the US EPA issued an update to the 1984 Ambient Water Quality Criteria for Ammonia (1999 Update). In both of the criteria documents, the US EPA acknowledged that ammonia toxicity may be dependent on the ionic composition of the exposure water, but the effects and understanding of these effects were insufficient to allow inclusion of them in the national criteria derivation. The 1999 Update states that these effects will "have to be addressed using water-effect ratios or other site-specific approaches" (US EPA, 1999). EPA acknowledges that it is possible that WERs for ammonia might be substantially different from 1 if there is an interaction with other pollutants or if there is a substantial difference in ionic composition (US EPA, 1999, Appendix 9). Studies cited in the 1999 Update include several studies done to investigate the impacts of the ionic composition of the exposure water on the toxicity of ammonia to a number of species, including Atlantic salmon, lake trout, rainbow trout, *Ceriodaphnia dubia*, and *Hyalella azteca*.

The results of these studies indicate that the toxicity of ammonia may be reduced in waterbodies similar to those found in Southern California with high hardness and elevated concentrations of certain ions (calcium, sodium, and potassium). Because the waterbodies in Los Angeles County are primarily effluent-dominated, the hardness and ionic concentrations in these waterbodies are much higher than the concentrations found in the laboratory dilution water used in the studies that were the basis for the ammonia criteria. For this reason, there is a potential to develop a WER for ammonia in these waterbodies.

III. Methodology

When developing WERs for ammonia, the US EPA recommends the procedures outlined in "Interim Guidance on Determination and Use of Water-Effect Ratios for Metals" (US EPA, 1994). The methodology used to develop the proposed site-specific objectives is consistent with this guidance and with US EPA's "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985).

(Original language edited to relate statute requirement for external scientific review clearly to topics that will be subject to review)

PROPOSED AMMONIA SITE-SPECIFIC OBJECTIVES FOR THE LOS ANGELES, SANTA CLARA AND SAN GABRIEL RIVERS AND THEIR TRIBUTARIES

Description of Scientific Issues to be addressed by Peer Reviewers

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 portion of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review.

1. **Use of the WER approach along with the "Guidelines for Deriving Numerical Water Quality Criteria for Protection of Aquatic Organisms and their Uses" to develop SSOs for these waters.**

   In both of the 1999 Update and the earlier 1984 Criteria Document, the US EPA acknowledged that ammonia toxicity may be dependent on the ionic composition of the exposure water, but the effects and understanding of these effects were insufficient to allow inclusion of them in the national criteria derivation. The 1999 Update states that these effects will "have to be addressed using water-effect ratios or other site-specific approaches" (US EPA, 1999). EPA acknowledges that it is possible that WERs for ammonia might be substantially different from 1 if there is an interaction with other pollutants or if there is a substantial difference in ionic composition (US EPA, 1999, Appendix 9). Studies cited in the 1999 Update include several studies done to investigate the impacts of the ionic composition of the exposure water on the toxicity of ammonia to a number of species, including Atlantic salmon, lake trout, rainbow trout, *Ceriodaphnia dubia*, and *Hyalella azteca*.

   The results of these studies indicate that the toxicity of ammonia may be reduced in waterbodies similar to those found in Southern California with high hardness and elevated concentrations of certain ions (calcium, sodium, and potassium). Because the waterbodies in Los Angeles County are primarily effluent-dominated, the hardness and ionic concentrations in these waterbodies are much higher than the concentrations found in the laboratory dilution water used in the studies that were the basis for the ammonia criteria. For this reason, there is a potential to develop a WER for ammonia in these waterbodies.

2. **Selecting *Hyalella azteca* as the primary species and fathead minnow as the secondary species in the WER study.**

Based on requirements in the WER guidance (US EPA, 1994), *Hyalella azteca* was chosen as the primary test species for the study. In the 1999 Update, the 30-day average (chronic) criterion was developed based on a limited number of chronic toxicity studies. The most sensitive species used in the development of the criterion was *Hyalella azteca* (see 1999 Update, p. 76). Uwe Borgmann conducted the chronic study used in the development of the criteria in 1994. Borgmann also conducted acute toxicity tests on *Hyalella* that indicate that hardness and concentrations of certain ions may have a significant impact on the toxicity of ammonia to *Hyalella*. As required in the WER guidance, the endpoint of the *Hyalella* chronic toxicity test is close to, but not lower than, the chronic criterion for these waterbodies at the pH values observed in the waterbodies. The *Hyalella* acute toxicity endpoint value is higher than the acute criterion for these waterbodies. Additionally, initial tests have demonstrated that the conditions in these rivers significantly affect the toxicity of ammonia to this species. For these reasons, *Hyalella* is an appropriate species to use in the development of a WER for these waterbodies.

The WER guidance requires that at least one test be conducted with a secondary species to confirm the results with the primary species. Based on a review of the 1999 Update and other studies that have been conducted and given that all the waterbodies in question are designated as warm water habitat (WARM), the secondary species used in the study was the fathead minnow (*Pimephales promelas*). The fathead minnow is the 4th most sensitive species used in the development of the chronic criterion in the 1999 Update.

3. **Use of acute tests to develop chronic WERs.**

The magnitude of a WER is likely to depend on the sensitivity of the test used to determine the WER. More sensitive tests are expected to result in higher WERs and less sensitive tests will result in WERs closer to 1 (USEPA, 1994). For the purposes of this study, acute *Hyalella* studies are the basis of the development of the chronic WER. As expected, the acute toxicity tests resulted in a lower WER than the chronic studies. The resulting SSO is therefore conservative. Additionally, the shorter and less costly acute studies allowed more studies to be conducted. Finally, the acute toxicity test for *Hyalella* is a more frequently used and established test than the chronic toxicity test so there are more data from other laboratories to compare to the monitoring results. The WER guidance specifically outlines that the endpoint of the test is the determining factor for selecting the test, not whether or not the test is chronic or acute. As a result, according to the guidance, a WER developed using acute toxicity tests may be applied to a chronic criterion and vice versa as long as the endpoint of the primary test is not lower than the criterion being adjusted (see discussion under #2 above).

4. **The decisions regarding the sampling design (i.e. sampling locations, frequency and seasonality).**

The *Interim Guidance for the Development of Water Effects Ratios for Metals* (EPA, 1994) specifies the minimum number of samples and types of samples to be collected for the development of a WER. The guidance requires at least three samples, two of which should be collected within 1 to 2 times the design flow of the waterbody and one collected in flows 2 to 10 times the design flow. The guidance does not have specific

requirements for the number of sampling locations that are required. The only requirement is that the number of sampling locations be "sufficient to characterize the site to which the SSO will apply." To avoid dilution of the site water samples during toxicity testing, the ammonia concentration in the site water needs to be as low as possible. This requirement limits the choice of sampling locations to sites with sufficiently low ammonia concentrations. Additionally, site access is a consideration, especially for wet weather sampling, further restricting the choices of sampling locations. For this reason, only one location is used for each discharger at a location downstream of the discharge.

Samples were collected at ten stations, each downstream of a wastewater treatment plant. At all but one station, four acute *Hyalella azteca* toxicity tests and one chronic *Pimephales promelas* (fathead minnow) test were collected. Additionally, at five stations, a chronic *Hyalella azteca* test was conducted to confirm that the use of acute tests to establish WER values was appropriately conservative for the purposes of this study. As a result of some QA/QC problems with the analysis of some samples, four acute *Hyalella* tests, two chronic *Hyalella* tests and three chronic fathead minnow tests were rejected and not used in the study analysis. Therefore, a total of 35 acute *Hyalella* tests, three *Hyalella* chronic tests, and seven chronic fathead minnow tests were successfully conducted during this study. The acute *Hyalella* tests were conducted during both dry and wet weather to assess the impacts of different seasons on the WER. Sampling began in January 2002 and was completed in February 2003. In addition, an initial study to assess the potential for developing a WER for ammonia was conducted in October 2000 at two sites on the Los Angeles River and at two sites on the San Gabriel River.

5. (a). Use of the laboratory toxicity tests in the final calculation of the WERs and SSOs.
(b). The decisions to retain or reject problematic toxicity tests.

All tests were reviewed and a summary of all the QA/QC requirements in the WER is included in the technical report. Although a number of deviations from the testing protocol were determined, only a few were considered to have a significant impact on the test results. Listed below are the two criteria used to determine if a test was unacceptable for the purposes of the study:

1. Survival in the laboratory dilution water control test was below the acceptable level for the test.
2. Dissolved oxygen levels in the test were below the minimum required value for more than 10% of samples collected during the testing period.

In some cases, control survival in the site water was below the required survival rate. These tests were still considered acceptable as long as the survival rate in the laboratory dilution water control was acceptable, because the control samples in site water all contained some ammonia that might have impacted the survival of the test organisms. These two criteria were used to eliminate unacceptable test results from the WER analysis because the EPA ammonia criteria documents used both the control survival and the dissolved oxygen levels to determine whether or not a particular study would be included in the calculation of the national ammonia criteria. Additionally, it was clear from the data review that these two issues had impacted the results of at least some of the tests that failed the criteria.

6. The methodology for calculating the final WERs and SSOs.

The calculation of the final WER for the study is based on the process outlined in the WER guidance document. The process involves calculating WERs for each of the dry weather events and taking the adjusted geometric mean of those WERs. That result is then compared to the WER calculated for wet weather events (hWER) to determine the final WER (fWER).

The WER guidance procedure places a large emphasis on the wet weather sample and the results obtained during wet weather. During the calculation of the wet weather hWERs, it became clear that the determination of the hWER was significantly impacted by the assumptions used in calculating the hWER, especially the flow conditions. Because the flow conditions are highly variable in Southern California, the use of a hWER based on a flow condition that could change dramatically over a very short period of time is difficult to justify. Consequently, the appropriateness of using the wet weather hWER versus the adjusted geometric mean of the dry weather WERs was evaluated.

The hWER calculations generally result in wet weather hWERs that are significantly higher than the adjusted geometric mean of the dry weather WER. The one exception is LA2 where the hWER drives the fWER using the calculation conditions chosen. However, because the choice of calculation conditions causes such variability in the hWER, under other wet weather conditions, the hWER may not be the lowest value. Over the course of the storm at LA2, the hWER was estimated to range from 1.0 to 409 based on the changing flow conditions in the river.

Additionally, the chronic objective is the only objective being adjusted by the fWER. The chronic objective is based on a 30-day averaging period. Wet weather events in Southern California occur over a matter of hours to days, but generally do not last for weeks at a time. Therefore, the application of a hWER based on a short-term condition to a 30-day chronic objective is not appropriate. Therefore, it was determined that the appropriate approach for this study was to use the adjusted geometric mean of the dry weather events as the fWER for all of the sites.

To calculate the SSOs for a waterbody reach, a new criteria equation was developed. Each equation was calculated based on EPA guidance for determining aquatic life criteria (US EPA, 1985). The SSOs are all equal to the pH relationship multiplied by the lower of 1) the *Hyalella* value adjusted by the WER or 2) the lowest fish value. This ensures that the SSOs are protective of both fish and invertebrates.

7. **The rationale of only adjusting the invertebrate data (GMCVs) in the national dataset to derive site specific objective equations given the differences in observed WERs between fish and invertebrates.**

During the testing, it became clear that a WER greater than 1.0 for the sensitive invertebrate species, *Hyalella*, occurred in the waterbodies, but a WER for a sensitive fish species, fathead minnow, was closer to 1. Consequently, an adjustment was made to the analytical approach, based on discussions with the Technical Advisory Committee (TAC) for the study, to take this fact into consideration. Specifically, to develop the SSOs for ammonia, the final WERs calculated from the *Hyalella* toxicity tests were used to

revise the invertebrate portion of the criterion equation, whereas the fish portion of the equation was not revised. After the adjustments to the invertebrate portion of the equation, the criterion was recalculated to determine the SSO. In these calculations, the objective is determined by the lower of 1) the temperature-adjusted *Hyalella* Genus Mean Chronic Value (GMCV) and 2) the lowest fish GMCV. This approach results in a SSO that is protective of both invertebrate and fish species.

8. **The decision to use the criteria pH relationship (from the US EPA 1999 Update) rather than a study-specific pH relationship for *Hyalella* to calculate the fWERs and SSOs for the study.**

The TAC requested that the pH relationship for *Hyalella* be examined to determine whether or not it matched the pH relationship developed in the 1999 Update. The pH relationship is a critical part of the study because it is used to adjust the results from the laboratory dilution water tests to equivalent results at the same pH as the site water (before the WER is calculated). A separate pH study was conducted and the results of that study as well as the results from all of the laboratory dilution water tests were compared to the criteria pH relationship to determine if differences existed that justified the development of a separate pH relationship for *Hyalella*. The comparison demonstrated that, at least for the average pH values found in the waterbodies in this study (7.34 to 8.05), the *Hyalella* pH relationship does not appear to be significantly different from the criteria pH relationship. Additionally, the use of a pH relationship developed based on the study would have resulted in WERs that are higher than the WERs calculated using the EPA pH relationship. So the use of the EPA pH relationship is a conservative approach to developing the WERs and SSOs for the study. As a result, a separate pH relationship was not used to calculate the WERs and SSOs for the study.

9. **Use of the recommended SSOs to protect Threatened and Endangered species.**

After the SSO values were calculated, the results were compared to the toxicity thresholds for any rare, endangered, threatened, or locally important species present in the waterbodies to ensure that the results were protective of those species.

10. **The decision by Regional Board staff, based on the results of the study, to recommend that the Board adopt reach-specific 30-day average objective equations (rather than watershed-wide SSOs or one SSO for all three watersheds).**

The variability in fWERs between sites and watersheds is not very significant, ranging from 1.395 to 2.303. For the most part, the watershed fWERs and overall fWER for the study are all around 2. To determine whether or not the differences between the sites were significant, an analysis of variance (ANOVA) was conducted. This analysis basically compares the means of the WERs collected at each site, the variance of the WERs, and information about the entire dataset to determine if the results are statistically different at a 95% confidence level. The results demonstrated that all of the WERs were statistically similar at the 95% confidence level except BW1 and SGR2. Because differences were seen between the Burbank Western Wash and the San Gabriel River, the chosen approach for this study was to use a site-by-site approach to account for the variability observed in the waterbodies and account for the possible differences in the ions causing the WER as demonstrated by the water quality analysis comparison.

The Big Picture

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

(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."

PROPOSED AMMONIA SITE-SPECIFIC OBJECTIVES FOR THE LOS ANGELES, SANTA CLARA AND SAN GABRIEL RIVERS AND THEIR TRIBUTARIES

Individuals Involved in Development of Basin Plan Amendment

Consultant
Larry Walker Associates - Ashli Cooper Desai

Technical Advisory Committee
Charles Delos, US EPA Headquarters
Gary Chapman, Paladin Water Quality Consulting
Steve Bay, SCCWRP

Regulated Community
Los Angeles County Sanitation Districts – Beth Bax
City of Los Angeles, Bureau of Sanitation – Shahrouzeh Saneie
City of Burbank – Rodney Andersen

US EPA Region IX
Robyn Stuber
Terry Fleming

Coordinating Committee

Name	Organization
Ron Bottorff	FOSCR
Jacqueline Lambrichts	FOSGR
Rick Harter	LASGWRC
Leslie Mintz	Heal the Bay
Bill Depoto	LACDPW
Mauricio Cardenas	DFG
Bill Reeves	SWRCB
(No individual identified)	FOLAR
Denise Steurer	USFWS
Karen Evans	USFWS
Heather Merenda	City of Santa Clarita

State Water Resources Control Board

Division of Water Quality

1001 I Street • Sacramento, California 95814 • (916) 341-5455
Mailing Address: P.O. Box 100 • Sacramento, California • 95812-0100
Fax (916) 341-5584 • http://www.waterboards.ca.gov

Alan C. Lloyd, Ph.D.
Agency Secretary

Arnold Schwarzenegger
Governor

The Regents of the University of California, Berkeley
SWRCB Contract # 11-135-240, EXHBIT A, ATTACHMENT 2

TO: John H. Robertus
Executive Officer
San Diego Regional Water Quality Control Board

Original Signed By
FROM: Gerald W. Bowes, Ph.D.
Chief, Toxicology and Peer Review Section
DIVISION OF WATER QUALITY

DATE: October 14, 2005

SUBJECT: PEER REVIEWERS FOR PROPOSED BASIN PLAN AMENDMENT INCORPORATING THE TMDLs FOR INDICATOR BACTERIA AT SAN DIEGO BAY AND DANA POINT HARBOR SHORELINES

In response to your request for peer reviewers for the proposed Basin Plan Amendment identified above, I am pleased to send you the name of two reviewers who have been selected to perform this review. These people have been approved by the University of California, Office of the President (UCOP), based on its review of a COI Disclosure form that each was required to complete.

The reviewers' names are given below. Please confirm with them that the review material should be sent to the address indicated:

1. Name and contact information for Peer Reviewer No. 1

2. Name and contact information for Peer Reviewer No. 2

I am providing biographical information for Professors _____ and _____ with this letter.

You should now contact Professors _____ and _____ immediately. Let them know you have been notified that they will be the external reviewers for your proposed

California Environmental Protection Agency

Recycled Paper

Board action. Also, tell them when to expect the material for review. The letter of request to me provided this information, and reviewer candidates' acceptance of the assignment often is conditional on their availability at that time. If the date has changed, confirm with the reviewers that the new date is acceptable. Keep in periodic contact with each reviewer if the date is expected to change again. I would like to receive copies of these email transmittals to keep up-to-date. I am always contacted by reviewers and the University when delays in the process arise.

[* Language containing additional conflict of interest questions deleted.]

Your letter to the reviewers should include the same three attachments that you provided in your request letter to me. Be clear to them that the second attachment, which lists the components of the scientific basis of the proposed rule, will be the focus of the review.

When all interactions with them have been completed, please let me know for the peer review files I keep here. This information also is essential for the peer review tracking report I write each month, which is provided to Division management and our Executive Office.

My files also should include the peer reviewers' comments and Board responses, and I request that you send this information to me for the record as well.

If I can provide additional help, feel free to contact me at any time during the review process.

Attachments

* The conflict of interest review procedure for this new Interagency Agreement (#06-104-600-0) includes coverage of the two topics highlighted. There is no longer any need for Cal/EPA organizations to contact reviewers on them.

W:\Standards Section\other\Exhibit F Peer Review Guidance 101006.doc

California Environmental Protection Agency

Recycled Paper

**Supplement to Cal/EPA External Scientific Peer Review Guidelines –
Cal/EPA Interagency Agreement with University of California
Gerald W. Bowes, Ph.D.**

January 7, 2009

Guidance to Staff:

1. Revisions. If you have revised any part of the initial request, please stamp "Revised" on each page where a change has been made, and the date of the change. Clearly describe the revision in the cover letter to reviewers, which transmits the material to be reviewed. The approved reviewers have seen your original request letter and attachments during the solicitation process, and must be made aware of changes.

2. Documents requiring review. All important scientific underpinnings of a proposed science-based rule must be submitted for external peer review. The underpinnings would include all publications (including conference proceedings), reports, and raw data upon which the proposal is based. If there is a question about the value of a particular document, or parts of a document, I should be contacted.

3. Documents not requiring review. The Cal/EPA External Peer Review Guidelines note that there are circumstances where external peer review of supporting scientific documents is not required. An example would be "A particular work product that has been peer reviewed with a known record by a recognized expert or expert body." I would treat this allowance with caution. If you have any doubt about the quality of such external review, or of the reviewers' independence and objectivity, that work product - which could be a component of the proposal - should be provided to the reviewers.

4. Implementation review. Publications which have a solid peer review record, such as a US EPA Criteria document, do not always include an implementation strategy. The Cal/EPA Guidelines require that the implementation of the scientific components of a proposal, or other initiative, must be submitted for external review.

5. Identity of external reviewers. External reviewers should not be informed about the identity of other external reviewers. Our goal has always been to solicit truly independent comments from each reviewer. Allowing the reviewers to know the identity of others sets up the potential for discussions between them that could devalue the independence of the reviews.

6. Panel Formation. Formation of reviewer panels is not appropriate. Panels can take on the appearance of scientific advisory committees and the external reviewers identified through the Cal/EPA process are not to be used as scientific advisors.

7. Conference calls with reviewers. Conference calls with one or more reviewers can be interpreted as seeking collaborative scientific input instead of critical review. Conference calls with reviewers are not allowed.

Guidance to Reviewers from Staff:

1. Discussion of review.

   Reviewers are not allowed to discuss the proposal with individuals who participated in development of the proposal. These individuals are listed in Attachment 3 of the review request.

   Discussions between staff and reviewers are not permitted. Reviewers may request clarification of certain aspects of the review process or the documents sent to them.

   Clarification questions and responses must be in writing. Clarification questions about reviewers' comments by staff and others affiliated with the organization requesting the review, and the responses to them, also must be in writing. These communications will become part of the administrative record.

   The organization requesting independent review should be careful that organization reviewer communications do not become collaboration, or are perceived by others to have become so. The reviewers are not technical advisors. As such, they would be considered participants in the development of the proposal, and would not be considered by the University of California as external reviewers for future revisions of this or related proposals. The statute requiring external review of science-based rules proposed by Cal/EPA organizations prohibits participants serving as peer reviewers.

2. Disclosure of reviewer Identity and release of review comments.

   Confidentiality begins at the point a potential candidate is contacted by the University of California. Candidates who agree to complete the conflict of interest disclosure form should keep this matter confidential, and should not inform others about their possible role as reviewer.

   Reviewer identity may be kept confidential until review comments are received by the organization that requested the review. After the comments are received, reviewer identity and comments must be made available to anyone requesting them.

   Reviewers are under no obligation to disclose their identity to anyone enquiring. It is recommended reviewers keep their role confidential until after their reviews have been submitted.

3. Requests to reviewers by third parties to discuss comments.

   After they have submitted their reviews, reviewers may be approached by third parties representing special interests, the press, or by colleagues. Reviewers are under no obligation to discuss their comments with them, and we recommend that they do not.

   All outside parties are provided an opportunity to address a proposed regulatory action during the public comment period and at the Cal/EPA organization meeting where the

proposal is considered for adoption. Discussions outside these provided avenues for comment could seriously impede the orderly process for vetting the proposal under consideration.

4. Reviewer contact information.

The reviewer's name and professional affiliation should accompany each review. Home address and other personal contact information are considered confidential and should not be part of the comment submittal.

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:

Attention: Dr. Gerald W. Bowes
Office of Research, Planning and Performance
State Water Resources Control Board
1001 I Street, 16th Floor
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 4)
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 1, 2, 3, 4, and 5). 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.

Exhibit B
Budget Detail and Payment Provisions

C. The State's obligation to make any payment under this contract shall be suspended during such time as the Budget Act covering that fiscal year has not been approved by the Legislature and signed by the Governor.

3. Payment

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).

C. Advance Payments

Advance payment of annual costs related to Contractor personnel, including associated Fringe Benefits and Facilities and Administrative costs, is agreed upon between and among the parties to this agreement. The Contractor may request advance payment of each Cal/EPA BDO upon DGS/OLS approval of the agreement and July 1 of each year thereafter. Advance Payment shall be due upon receipt of request / invoice for said payment.

BDO	Year 1	Year 2	Year 3	Year 4	Year 5	BDO Total
Cal/EPA	-0-	$ 2,000.00	$ 2,000.00	$ 2,000.00	$ 2,000.00	$ 8,000.00
ARB	$ 20,389.23	$ 47,962.48	$ 50,394.03	$ 50,394.03	$ 52,897.85	$222,037.61
DPR	$ 20,389.23	$ 15,000.00	$ 15,000.00	$ 15,000.00	$ 15,000.00	$ 80,389.23
DTSC	$ 20,389.23	$ 37,641.65	$ 37,641.65	$ 37,641.65	$ 37,641.65	$170,955.83
OEHHA	$ 20,389.23	$ 37,641.65	$ 37,641.65	$ 37,641.65	$ 37,641.65	$170,955.83
SWRCB	$ 20,389.22	$ 47,962.48	$ 50,394.03	$ 50,394.03	$ 52,897.85	$222,037.61
Year Total	$101,946.14	$188,208.25	$193,071.36	$193,071.36	$198,079.00	$874,376.11

Cal/EPA or its BDOs may request that Contractor utilize Contractor personnel supported by the advance payment of annual costs under this agreement to coordinate similar types of work under other, stand-alone, agreements between Cal/EPA or its BDOs and Contractor. Such work will be at the discretion of Contractor, to the extent that personnel are available.

4. Amounts Payable

A. The amounts payable under this agreement shall not exceed for the **Cal/EPA**:

1) $ 1,670.00 for the budget period of 12/15/11 through 06/30/12.
2) $ 4,500.00for the budget period of 07/01/12 through 06/30/13.
3) $ 4,500.00 for the budget period of 07/01/13 through 06/30/14.

Exhibit B
Budget Detail and Payment Provisions

4) $ 4,500.00 for the budget period of 07/01/14 through 06/30/15.
5) $ 4,500.00 for the budget period of 07/01/15 through 06/30/16.
$ 19,670.00 Total

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

1) $ 54,139.23 for the budget period of 12/15/11 through 06/30/12.
2) $ 70,462.48 for the budget period of 07/01/12 through 06/30/13.
3) $ 72,894.03 for the budget period of 07/01/13 through 06/30/14.
4) $ 72,894.03 for the budget period of 07/01/14 through 06/30/15.
5) $ 75,397.85 for the budget period of 07/01/15 through 06/30/16.
$345,787.62 Total

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

1) $ 31,639.23 for the budget period of 12/15/11 through 06/30/12.
2) $ 26,250.00 for the budget period of 07/01/12 through 06/30/13.
3) $ 26,250.00 for the budget period of 07/01/13 through 06/30/14.
4) $ 22,500.00 for the budget period of 07/01/14 through 06/30/15.
5) $ 22,500.00 for the budget period of 07/01/15 through 06/30/16.
$129,139.23 Total

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

1) $ 65,389.23 for the budget period of 12/15/11 through 06/30/12.
2) $105,141.65 for the budget period of 07/01/12 through 06/30/13.
3) $105,141.65 for the budget period of 07/01/13 through 06/30/14.
4) $105,141.65 for the budget period of 07/01/14 through 06/30/15.
5) $105,141.65 for the budget period of 07/01/15 through 06/30/16.
$485,955.83 Total

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

1) $ 42,889.23 for the budget period of 12/15/11 through 06/30/12.
2) $ 82,641.65 for the budget period of 07/01/12 through 06/30/13.
3) $ 60,141.65 for the budget period of 07/01/13 through 06/30/14.
4) $ 60,141.65 for the budget period of 07/01/14 through 06/30/15.
5) $ 60,141.65 for the budget period of 07/01/15 through 06/30/16.
$305,955.83 Total

Exhibit B
Budget Detail and Payment Provisions

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

1) $ 76,639.23 for the budget period of 12/15/11 through 06/30/12.
2) $149,212.48 for the budget period of 07/01/12 through 06/30/13.
3) $151,644.03 for the budget period of 07/01/13 through 06/30/14.
4) $151,644.03 for the budget period of 07/01/14 through 06/30/15.
5) $154,147.85 for the budget period of 07/01/15 through 06/30/16.
$683,287.61 Total

G. 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. Payment of Subcontractors

A. Payments to subcontractors will be processed by the Contractor, who shall ensure subcontractor invoices are directed to the University Project Manager. Contractor may authorize payment for completed services, after confirming with the Cal/EPA Project Manager that all services were satisfactorily fulfilled.

6. 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 # 7 in this exhibit entitled, "Recovery of Overpayments" for more information.

Exhibit B
Budget Detail and Payment Provisions

F. Contractor shall submit to the Cal/EPA Project Manager a quarterly accounting of personnel time in hours and personnel costs in dollars, including salaries, benefits and indirect costs, and all subcontractor costs, associated with this Agreement.

7. 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 1
Budget
Year 1 (12/15/2011 through 6/30/2012)

Personnel		
100% FTE Project Manager *		$ 54,040
10% FTE Administrative Officer *		$ 4,063
	Total Personnel	$ 57,103
Fringe Benefits **		$ 13,134
Operating Expenses		$ -0-
Travel		$ -0-
Subcontracts ***		
Subcontractor: Professors at State, National Academy of Sciences, University of California State University, Scientific Institution of Higher Learning (or any combination of these entities), Scientist or group of scientists of comparable stature and qualifications, or private universities.		
	Total Subcontracts	$136,336
Other Costs		
Stipend to Project Director, Prof. Sposito		$ 2,708
Stipend to UC Anonymous Board members		$ 8,613
	Total Other Costs	$ 11,321
Indirect Costs (25% of total direct costs)		$ 54,473
	Total Costs	$272,366

* Pay rate of Project Manager is as Academic Coordinator II Step 12, $97,920 / year.
* Pay rate of Administrative Officer is $75,000 / year.

** Fringe Benefit Rate: 23% (of direct salary expense)

*** Subcontracts: The dollar amount presented is based on a combination of Scientific / Economic and Curriculum reviews. It is anticipated the reviewer will require 12 hours to complete Scientific / Economic Reviews and 2.5 hours for Curriculum Reviews. The anticipated average hourly rate charged by each reviewer is $250/hour. The actual hourly rate and hours billed may vary.

Advance Payment Due 12/15/2011 $101,946.14
Advance payment in accordance with Exhibit B, Provision 3.C.

Exhibit B, Attachment 2
Budget
Year 2 (07/01/2012 through 6/30/2013)

Personnel		
100% FTE Project Manager *		$ 97,920
10% FTE Administrative Officer		$ 7,500
	Total Personnel	$105,420
Fringe Benefits **		$ 24,247
Operating Expenses		$ -0-
Travel		$ -0-
Subcontracts ***		
Subcontractor: Professors at State, National Academy of Sciences, University of California State University, Scientific Institution of Higher Learning (or any combination of these entities), Scientist or group of scientists of comparable stature and qualifications, or private universities.		
	Total Subcontracts	$200,000
Other Costs		
Stipend to Project Director, Prof. Sposito		$ 5,000
Stipend to UC Anonymous Board members		$ 15,900
	Total Other Costs	$ 20,900
Indirect Costs (25% of total direct costs)		$ 87,641
	Total Costs	$438,208

* Pay rate of Project Manager is as Academic Coordinator II Step 12, $97,920 / year.
* Pay rate of Administrative Officer is $75,000 / year.

** Fringe Benefit Rate: 23% (of direct salary expense)

*** Subcontracts: The dollar amount presented is based on a combination of Scientific / Economic and Curriculum reviews. It is anticipated the reviewer will require 12 hours to complete Scientific / Economic Reviews and 2.5 hours for Curriculum Reviews. The anticipated average hourly rate charged by each reviewer is $250/hour. The actual hourly rate and hours billed may vary.

Advance Payment Due 7/1/2012 $188,208.25
Advance payment in accordance with Exhibit B, Provision 3.C.

Exhibit B, Attachment 3
Budget
Year 3 (07/01/2013 through 6/30/2014)

Personnel		
100% FTE Project Manager *		$100,858
10% FTE Administrative Officer		$ 7,725
	Total Personnel	$108,583
Fringe Benefits **		$ 24,974
Operating Expenses		$ -0-
Travel		$ -0-
Subcontracts ***		
Subcontractor: Professors at State, National Academy of Sciences, University of California State University, Scientific Institution of Higher Learning (or any combination of these enfities), Scientist or group of scientists of comparable stature and qualifications, or private universities.		
	Total Subcontracts	$182,000
Other Costs		
Stipend to Project Director, Prof. Sposito		$ 5,000
Stipend to UC Anonymous Board members		$ 15,900
	Total Other Costs	$ 20,900
Indirect Costs (25% of total direct costs)		$ 84,114
	Total Costs	$420,571

* Pay rate of Project Manager is as Academic Coordinator II Step 12, $100,858 / year.
* Pay rate of Administrative Officer is $77,250 / year.

** Fringe Benefit Rate: 23% (of direct salary expense)

*** Subcontracts: The dollar amount presented is based on a combination of Scientific / Economic and Curriculum reviews. It is anticipated the reviewer will require 12 hours to complete Scientific / Economic Reviews and 2.5 hours for Curriculum Reviews. The anticipated average hourly rate charged by each reviewer is $250/hour. The actual hourly rate and hours billed may vary.

Advance Payment Due 7/1/2013 $193,071.36
Advance payment in accordance with Exhibit B, Provision 3.C.

Exhibit B, Attachment 4
Budget
Year 3 (07/01/2014 through 6/30/2015)

Personnel		
100% FTE Project Manager *		$100,858
10% FTE Administrative Officer		$ 7,725
	Total Personnel	$108,583
Fringe Benefits **		$ 24,974
Operating Expenses		$ -0-
Travel		$ -0-
Subcontracts ***		
Subcontractor: Professors at State, National Academy of Sciences, University of California State University, Scientific Institution of Higher Learning (or any combination of these entities), Scientist or group of scientists of comparable stature and qualifications, or private universities.		
	Total Subcontracts	$179,000
Other Costs		
Stipend to Project Director, Prof. Sposito		$ 5,000
Stipend to UC Anonymous Board members		$ 15,900
	Total Other Costs	$ 20,900
Indirect Costs (25% of total direct costs)		$ 83,364
	Total Costs	$416,821

* Pay rate of Project Manager is as Academic Coordinator II Step 12, $100,858 / year.
* Pay rate of Administrative Officer is $77,250 / year.

** Fringe Benefit Rate: 23% (of direct salary expense)

*** Subcontracts: The dollar amount presented is based on a combination of Scientific / Economic and Curriculum reviews. It is anticipated the reviewer will require 12 hours to complete Scientific / Economic Reviews and 2.5 hours for Curriculum Reviews. The anticipated average hourly rate charged by each reviewer is $250/hour. The actual hourly rate and hours billed may vary.

Advance Payment Due 7/1/2013 $193,071.36
Advance payment in accordance with Exhibit B, Provision 3.C.

Exhibit B, Attachment 5
Budget
Year 5 (07/01/2015 through 06/30/2016)

Personnel		
100% FTE Project Manager *		$103,883
10% FTE Administrative Officer		$ 7,957
	Total Personnel	$111,840
Fringe Benefits **		$ 25,723
Operating Expenses		$ -0-
Travel		$ -0-
Subcontracts ***		
Subcontractor: Professors at State, National Academy of Sciences, University of California State University, Scientific Institution of Higher Learning (or any combination of these entities), Scientist or group of scientists of comparable stature and qualifications, or private universities.		
	Total Subcontracts	$179,000
Other Costs		
Stipend to Project Director, Prof. Sposito		$ 5,000
Stipend to UC Anonymous Board members		$ 15,900
	Total Other Costs	$ 20,900
Indirect Costs (25% of total direct costs)		$ 84,366
	Total Costs	$421,829

* Pay rate of Project Manager is as Academic Coordinator II Step 12, $103,883 / year.
* Pay rate of Administrative Officer is $79,570 / year.

** Fringe Benefit Rate: 23% (of direct salary expense)

*** Subcontracts: The dollar amount presented is based on a combination of Scientific / Economic and Curriculum reviews. It is anticipated the reviewer will require 12 hours to complete Scientific / Economic Reviews and 2.5 hours for Curriculum Reviews. The anticipated average hourly rate charged by each reviewer is $250/hour. The actual hourly rate and hours billed may vary.

Advance Payment Due 7/1/2013 $198,079
Advance payment in accordance with Exhibit B, Provision 3.C.

EXHIBIT D
SPECIAL TERMS AND CONDITIONS

1. DISPUTE RESOLUTION PROCESS: Any dispute arising under or relating to the terms of this Agreement, or related to the performance hereunder, which is not disposed of by Agreement shall be decided by the Contract Manager, who shall reduce such decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contract Manager shall be final and conclusive unless, within fifteen (15) calendar days from the date of receipt of such copy, the Contractor mails or otherwise delivers a written appeal to the State Water Resources Control Board Executive Director. The decision of the Executive Director, or authorized representative, on such appeal shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by any substantial evidence. In connection with any appeal under this Section, the Contractor shall be afforded an opportunity to be heard and to offer evidence and argument in support of the appeal. Pending final decision on any dispute hereunder, the Contractor shall proceed diligently with the performance of the Agreement work as directed by the Contract Manager unless the Contractor has received notice of termination. Decisions on any disputes hereunder may include decisions of both fact and law; provided, however, that nothing herein shall be construed as making final any decision on a question of fact or law in the event of any subsequent legal proceeding before a court of competent jurisdiction.

   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 CFR 31.70)

2. RIGHTS IN DATA: The Contractor agrees that all data, plans, drawings, specifications, reports, computer programs, operating manuals, notes, and other written or graphic work produced in the performance of this Agreement are subject to the rights of the State as set forth in this section. The State shall have the right to reproduce, publish, and use all such work, or any part thereof, in any manner and for any purposes whatsoever and to authorize others to do so. If any such work is copyrightable, the Contractor may copyright the same, except that, as to any work which is copyrighted by the Contractor, the State reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, and use such work, or any part thereof, and to authorize others to do so. (40 CFR 31.34, 31.36)

3. DISCLOSURE REQUIREMENTS: Any document or written report prepared in whole or in part pursuant to this Agreement shall contain a disclosure statement indicating that the document or written report was prepared through Agreement with the State. The disclosure statement shall include the Agreement number and dollar amount of all Agreements and subcontracts relating to the preparation of such documents or written reports. The disclosure statement shall be contained in a separate section of the document or written report.

   If the Contractor or subcontractor(s) are required to prepare multiple documents or written reports, the disclosure statement may also contain a statement indicating that the total Agreement amount represents compensation for multiple documents or written reports.

   The Contractor shall include in each of its subcontracts for work under this Agreement a provision which incorporates the requirements stated within this Section. (Gov. Code 7550, 40 CFR 31.20)

4. PERMITS, WAIVER, REMEDIES AND DEBARMENT: The Contractor shall procure all permits and licenses necessary to accomplish the work contemplated in this Agreement, pay all charges and fees, and give all notices necessary and incidental to the due and lawful prosecution of the work.

   Any waiver of rights with respect to a default or other matter arising under the Agreement at any time by either party shall not be considered a waiver of rights with respect to any other default or matter.

   Any rights and remedies of the State provided for in this Agreement are in addition to any other rights and remedies provided by law.

   Contractor shall not subcontract with any party who is debarred or suspended or otherwise excluded from or ineligible for participation in federal assistance programs under Executive Order 12549, "Debarment and

EXHIBIT D
SPECIAL TERMS AND CONDITIONS

Suspension". Contractor shall not subcontract with any individual or organization on USEPA's List of Violating Facilities. (40 CFR, Part 31.35, Gov. Code 4477)

5. TRAVEL AND PER DIEM: Any reimbursement for necessary travel and per diem shall, unless otherwise specified in this agreement, be at the rates currently in effect, as established by the California Department of Personnel Administration (DPA). If the DPA rates change during the term of the agreement, the new rates shall apply upon their effective date and no amendment to this agreement shall be necessary. Local government agency, education and special districts will pay travel time and per diem according to their respective statutory requirements. No travel outside the state of California shall be reimbursed without prior authorization from the State Water Resources Control Board. Verbal authorization should be confirmed in writing. Written authorization may be in a form including fax or email confirmation.

6. CANCELLATION / TERMINATION:

   A. This agreement may be cancelled or terminated without cause by either party by 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 the SWRCB, 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.

7. BUDGET FLEXIBILITY:

   A. Subject to the prior review and approval of the contract manager, line items shifts of up to $25,000 or ten percent of the annual contract total, whichever is less, may be made up to a cumulative maximum of $25,000 or 10%, whichever is less, for all line item shifts over the life of the contract.

   B. There must be a substantial business justification for any shifts made. Fund shifts which increase Indirect, Overhead or General Expense line items are prohibited. Line item shifts may be proposed/requested by either the SWRCB or the Contractor in writing and must not increase or decrease the total contract amount allocated.

   C. Any line item shifts must be approved in writing by the Deputy Director of (managing division), or his or her designee, and must be sent to Contracts Office within 10 days of approval for inclusion in contract folder. If the contract is formally amended, any line item shifts agreed to by the parties must be included in the amendment.

8. FOUR-DIGIT DATE COMPLIANCE: Contractor warrants that it will provide only Four-Digit Date Compliant deliverables and/or services to the State. "Four Digit Date Compliant" deliverables and services can accurately process, calculate, compare, and sequence date data, including without limitation date data arising out of or relating to leap years and changes in centuries. This warranty and representation is subject to the warranty terms and conditions of this Agreement and does not limit the generality of warranty obligations set forth elsewhere herein.

9. COMPUTER SOFTWARE: Contractor certifies that it has appropriate systems and controls in place to ensure that state funds will not be used in the performance of this contract for the acquisition, operation or maintenance of computer software in violation of copyright laws.

EXHIBIT D
SPECIAL TERMS AND CONDITIONS

10. CONTRACT AMENDMENTS:

A. 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.

B. Any Board, Department or Office (BDO) signatory to this contract within CalEPA may approve additional funding as an amendment to support specific needs within the approved tasks without the approval of all other BDOs on the contract. Other types of amendments require approval by all BDO signatories.

11. POTENTIAL SUBCONTRACTORS: Nothing contained in this Agreement or otherwise, shall create any contractual relation between the SWRCB and any subcontractors, and no subcontract shall relieve the Contractor of his responsibility and obligations hereunder. The Contractor agrees to be as fully responsible to the SWRCB for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them as it is for the acts and omissions of persons directly employed by the Contractor. The Contractor's obligation to pay its subcontractors is an independent obligation from the SWRCB's obligation to make payments to the Contractor. As a result, the SWRCB shall have no obligation to pay or to enforce the payment of any moneys to any subcontractor.

12. SUBCONTRACTING: The Contractor is responsible for any work it subcontracts. Subcontracts must include all applicable terms and conditions of this Agreement. Any subcontracts, outside associates, or consultants required by the Contractor in connection with the services covered by this Agreement shall be limited to such individuals or firms as were specifically identified in the bid or agreed to during negotiations for this agreement, or as are specifically authorized by the Contract Manager during the performance of this Agreement. Any substitutions in, or addition to, such subcontractors, associates, or consultants shall be subject to prior written approval of the Contract Manager. Contractor warrants, represents and agrees that it and all its subcontractors, employees, and representatives shall at all times comply with all applicable laws, codes, rules, and regulations in the performance of this Agreement. Should SWRCB determine that the work performed by a subcontractor is substantially unsatisfactory and is not in substantial accordance with the contract terms and conditions, or that the subcontractor is substantially delaying or disrupting the process of work, SWRCB may request substitution of the subcontractor.

13. APPROVAL: This agreement is not valid until signed by both parties and approved by the Department of General Services, if required.

14. FORCE MAJEURE:

Except for defaults of subcontractors, neither party shall be responsible for delays or failures in performance resulting from acts beyond the control of the offending party. Such acts shall include but shall not be limited to acts of God, fire, flood, earthquake, other natural disaster, nuclear accident, strike, lockout, riot, freight embargo, public regulated utility, or governmental statutes or regulations superimposed after the fact. If a delay or failure in performance by the Contractor arises out of a default of its subcontractor, and if such default of its subcontractor, arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be liable for damages of such delay or failure, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required performance schedule.

EXHIBIT D
SPECIAL TERMS AND CONDITIONS

15. PROHIBITED PRACTICES:

The contractor warrants that the contract was not obtained through rebates, kickbacks, or other unlawful considerations either promised or paid to a board employee. Facts showing failure to adhere to this warranty may be cause for contract termination and recovery of damages under the rights and remedies due the board under the default provision of the contract due the board per Exhibit C, General Terms and Conditions, paragraph 7. Termination for Cause.

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.