

**Supplement to Cal/EPA External Scientific Peer Review Guidelines –
“Exhibit F” in Cal/EPA Interagency Agreement with University of California
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1. **REVISIONS.** If changes are made in the final, signed request for review, and before the review has begun, a revised request must be discussed with, and submitted to the review manager. Normally, this is the CalEPA program manager for scientific peer review. The accepted revision must clearly describe changes, and at the time of review initiation, be sent to the reviewers by the program manager as the basis for the review. The original final request had been sent earlier to candidate reviewers and discussed with them during an interview. Candidates that were eventually approved as reviewers, must clearly understand parts of the request have been changed, and where.

A revised cover letter must a) indicate in red text at the top right corner, “**Revised**” and date of revision; and b) be re-signed by the requesting party.

The cover letter also must describe in red text the nature of the changes and where they occur, e.g. in Attachment 2. “**Revised**” and date of revision must be typed in red text at the top right corner on each page where a change has been made. Revised text also must be highlighted in red, and presented in strikeout/underline format.

2. **DOCUMENTS REQUIRING REVIEW.** All scientific underpinnings of a proposed science-based rule must be submitted for external peer review. The underpinnings include all publications, conference proceedings, reports, model descriptions, and raw data upon which the proposal is based. Data from proprietary models cannot be used to support a proposal.
3. **DOCUMENTS NOT REQUIRING PEER 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." This allowance should be treated with caution. The context of the work product must be taken into account, and considered with respect to relevance to the proposal to be reviewed. The reviewers' independence and objectivity for the prior review must be considered. A safe approach would be to provide such a document to the reviewers, and let them decide if their review is needed, or at least for parts of the work product.
4. **REVIEW OF IMPLEMENTATION STRATEGY.** 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. **CONFIDENTIALITY OF REVIEWER IDENTITIES, AND REVIEWS.** External reviewers must not know the identity of other reviewers. Their identities can only be known to the CalEPA program manager for peer review (who manages the reviews), or other person delegated to managing the review. After the reviews have been completed and submitted by the program manager to the organization which requested the review, the timing of release of the reviews and identities of reviewers and their curriculum vitae, is a decision to be made by the organization, including participating legal staff.
6. **REQUESTS FROM REVIEWERS FOR ADDITIONAL SPECIFIC SUPPORTING DOCUMENTS, OR CLARIFICATION.** This should be provided to the requesting reviewer, and to all other reviewers to ensure all reviewers have the same information.
7. **USE OF PANELS.** 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.
8. **USE OF EXTERNAL EXPERTS TO ASSIST IN PREPARATION OF RESPONSES TO EXTERNAL REVIEWERS.** California Health and Safety Code Section 57004 directs external reviewers to critically analyze CalEPA staff-developed assumptions, findings, and conclusions as the basis for proposed science-based rules. These are derived from staff's review and interpretation of relevant scientific literature. They are described in the review request, Attachment 2.

Normally, staff prepares responses to reviewers' comments, which are reviewed by the respective executive offices. On rare occasions, staff may solicit outside expert assistance in preparing these responses. Staff must be careful that rules of confidentiality are followed by assisting experts to protect reviewers' identities and nature of the reviews. Each review sent to such experts must be marked, "Highly Confidential – Not to be Shared". Communications must be directly between the staff person designated as the contact for the assisting experts, and the experts.

Prior to this engagement, the CalEPA organization seeking outside assistance must ensure through a conflict of interest vetting process that the enlisted experts meet certain criteria. First, the experts must have no financial interest in the outcome of the review. Second, they have no working relationships with any private or public sector entity that would benefit by, or be restricted in some way by, the proposed regulation.

If the outside assistance takes the form of experts brought together as a panel (not recommended) with a designated chair, assuring confidentiality becomes more of a challenge. Further, a panel report implies the expert reviews represent a consensus of panel members on the stated conclusions. This would be misleading. The panel expertise is identified as a critical mass which collectively could cover the range of conclusions described as the basis for the proposed rule. It would mirror the critical mass expertise originally identified and approved as reviewers of the proposal itself. The reviewers agree to address one or a few of the conclusions, based on expertise. Similarly, staff is best served by receiving independent and objective comments from individual advising experts on the reviews, based on expertise.

The path taken to solicit such assisting experts, and the path back for this assistance, must be described and approved before such steps are taken. This must include a description of measures designed to protect reviewers' identities and the substance of their reviews.

Guidance to Reviewers:

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. The requests and responses 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 identities must 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, within a reasonable time period specified by legal staff.

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 made public by requesting CalEPA organization.

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, professional affiliation, and date should accompany each review. Home address and other personal contact information are considered confidential and should not be part of the comment submittal.