

Peer Review Process

The Alaska Department of Environmental Conservation (ADEC) has tasked Toxicology Excellence for Risk Assessment (TERA) with conducting an independent, expert peer review of the available reference doses (RfDs) for sulfolane. A sulfolane RfD will be used by ADEC to develop cleanup levels for groundwater in North Pole, Alaska. TERA is an independent non-profit organization with a mission to protect public health through the best use of toxicity and exposure information in the development of human health risk assessments. As a non-profit organization, TERA organizes independent peer reviews on chemical assessments or other risk assessment work products to meet the needs of public and private sponsors.

The purpose of the peer review is to convene a group of experts to evaluate the scientific basis and appropriateness of the document(s) and related conclusions. Peer review is a critical review of a work product that is conducted by qualified individuals who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the work. The peer review involves an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology, and conclusions of the material under review.

Generally the sponsor of the TERA peer review pays for the direct costs of conducting the peer review meeting and TERA's labor costs to organize and convene the peer review. TERA's responsibilities include identifying and recruiting scientists with relevant expertise, identifying and managing conflict of interest and bias issues, organizing and conducting the meeting, and drafting and finalizing the meeting report. The peer reviewers have been offered an honorarium for their service; some may accept and some may decline the honorarium offer.

TERA has developed its peer review and consultation program following principles highlighted by the U.S. Office of Management and Budget (OMB) and utilizing approaches used by U.S. EPA, the National Academy of Sciences, EPA's Science Advisory Board, and the International Life Sciences Institute (ILSI) Policies and Procedures for its Model Peer Review Center of Excellence.

Selection of the Panel and Evaluation of Potential Conflict of Interest and Bias Issues

The sulfolane peer reviewers are recognized technical experts who have been selected for their relevant scientific technical knowledge and independence. Collectively, the panel has expertise in toxicology, immunology, human health risk assessment, RfD methods and derivation, contaminated site assessments, biostatistics, and benchmark dose modeling. The experts have background and experience with the government, university, industry, and non-profit sectors. Each selected expert has been screened for potential conflicts of interest and every effort was made to avoid conflicts of interest and biases that would prevent a panel member from giving an independent opinion on the subject.

TERA, as the independent group convening the peer review, was solely responsible for selecting the panel. TERA's final selection of the panel members was based upon the

candidates' scientific experience and credentials, the overall need for coverage of the charge questions, conflict of interest and bias considerations, and the individuals' interest and availability. Experts serve on the panel as individuals and provide their personal scientific opinions on the issues under discussion during the meeting; they do not serve as representatives of their employers or any other group with whom they may be affiliated.

In order to protect the independence of the panel's review, the experts' names are not being shared or released prior to the meeting. TERA has not identified the panel members to ADEC or anyone other than the panel. Panel members have been asked to refrain from discussing the review with others.

Development of the Charge

TERA has reviewed the group of RfDs and the background document prepared by ADEC and developed the charge to peer reviewers. The purpose of the charge is to identify the important relevant scientific issues and questions, and provide a framework for the panel discussions. The sulfolane panel charge covers the key aspects and decision points for the derivation of an RfD. The charge also includes open ended questions to insure that the experts will cover all relevant issues in their discussions.

Prior to the Peer Review Meeting

TERA has been responsible for all preparations for the review including putting together a package of review materials, which is sent to the panel approximately one month prior to the meeting. The review package includes the ADEC background document, copies of the RfDs, key references, and the peer review charge. The panel will review these materials prior to the meeting. Panel members may identify additional references or analyses prior to the meeting and if they do, this information will be shared with other attendees.

The authors of the subject RfDs have been invited to attend the peer review meeting. They have also been invited to provide TERA with any additional information that they think the panel would find useful in reviewing the RfDs.

Prior to the meeting TERA will post information for the meeting on the TERA web site (<http://www.tera.org/Peer/index.html>), including the charge questions, ADEC's background document and a list of the materials provided to the experts. Those interested are invited to provide written technical comments on the materials that they think may be useful for the panel deliberations. These technical public comments will be posted to the web page and shared with the panel.

The Peer Review Meeting

The purpose of the peer review meeting is to have the expert panel evaluate the RfDs and reach conclusions based on the science. Therefore, the discussions will be limited to the panel members. During their discussions, the panel may seek clarification on the individual RfDs from the RfD authors. At several points in the agenda, the chair will ask the attending RfD authors if they have any clarifying questions for the panel.

The meeting chair will facilitate the panel in their discussions to cover the issues and questions from the charge. Individual panelists will be asked to share their opinions and defend them with scientific data and analysis. The panel will attempt to achieve consensus on the key points and charge questions. If unanimous consensus is not achieved, the meeting report will discuss minority opinions to reflect the full range of opinions of the panel.

Ground Rules for Meeting Observers

The peer review meeting will be open to the public and interested persons are invited to attend and observe. Observers are asked to register for the meeting in advance as space is limited. Observers are invited to listen and are expected to remain quiet during the meeting. It is important that the meeting attendees remember that the panel members must remain independent and should not be influenced by any party. Therefore, we will ask observers to refrain from discussing the RfDs or related issues with the panel members during the breaks unless a panel member initiates the discussion. Panel members will be asked to summarize any relevant conversations for the rest of the panel and audience when the meeting reconvenes after the break.

No pictures, audio, or visual recording, will be allowed at the meeting.

The purpose of the meeting is to obtain the consensus opinion of the panel of experts as a whole after their full deliberation and discussion of the RfDs. During the meeting, panelists will make statements and ask questions as they work through the issues to form their individual and collective opinions. Statements or opinions expressed during the discussions may not reflect the panelist's or the panel's final thinking on the subject. Therefore, it would be inappropriate to quote individual statements from the meeting. The final meeting report will contain the official recommendations and conclusions of the panel.

Meeting Report

TERA scientist(s) take notes of the discussions and prepare a draft meeting report that summarizes the panel's discussions, conclusions, and recommendations. This report will not be a transcript of the meeting; rather it will summarize the key discussions and conclusions. The report text will not attribute comments to specific panelists as it is the consensus opinion of the panel as a whole that is the important result of the peer review. During the finalization of the meeting report, the panel may clarify their conclusions; the panel's conclusions and recommendations are not final until the final meeting report is released.

If RfD authors or others speak at the meeting, the text summarizing their statements will be shared with that individual so that he or she can confirm the text's accuracy. The final meeting report will be the official record of the peer review and contain copies of any presentation slides, a list of attendees, panel biographical sketches and COI/bias information, handouts from the meeting, and any public comments. The meeting report will be made available on the TERA meeting web page.