Report of the NJDEP Science Advisory Board

Prepared by the Science Advisory Board Public Health Standing Committee

Review of Options for Peer Review of DSREH Human Health Risk Assessments

Approved by the NJDEP Science Advisory Board

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October 5, 2017

The following report has been issued by the Science Advisory Board to the Commissioner of the New Jersey Department of Environmental Protection

Response to the Charge Questions regarding:

Review of Options for Peer Review of DSREH Human Health Risk Assessments

This report was prepared by the Public Health Standing Committee and sent to the Science Advisory Board for review and approval. The Science Advisory Board based this final report on those recommendations from the Public Health Standing Committee.

Members of the Public Health Standing Committee include:

Mark Robson, Ph.D., M.P.H., Chairperson
Jerald A. Fagliano, M.P.H., Ph.D.
Elaine Z. Francis, Ph.D.
Michael Greenberg, Ph.D.
Michael Gochfeld, M.D., Ph.D.
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Steven Marcus, M.D.
Clifford Weisel, Ph.D.

NJDEP-SAB, Public Health Standing Committee Review of Options for Peer Review of DSREH Human Health Risk Assessments

<u>Introduction</u>

In 2015, the Public Health Standing Committee (PHSC) of the NJDEP-Science Advisory Board was tasked with reviewing and commenting on the Draft Guidance for the Development and Review of Human Health Risk Assessment Documents prepared by the NJDEP Division of Science Research and Environmental Health (DSREH). That document initially contained a stand-alone section that provided suggested options for peer-review of risk assessments prepared by the DSREH. With the approval of the NJDEP, the PHSC separated their assignment into two separate tasks: the review of the risk assessment guidance and the review of the options for peer-review. The PHSC's review of the risk assessment guidance was completed in 2016. This report contains the PHSC's review and response to charge questions relating to the options for peer-review.

Response of PHSC/SAB on Peer-Review of RAs

<u>Charge Question #1</u> - Please comment on whether the guidance document, in general, provides clear, reproducible, appropriate and transparent options for the peer review of Division of Science, Research and Environmental Health human health risk assessments.

The Public Health Committee (Committee) finds that the document under review is clear, reproducible, appropriate and transparent as far as laying out the options for peer review of DSREH assessments. The Committee recommends that if management of the peer review process is to be conducted by an academic or a for-profit consulting concern, the umbrella management process should be put into place prior to, and in anticipation of, any risk assessments that would be designated for peer-review via those processes.

The Committee notes that under the revised guidance document Option 2 (a university administers peer review) includes the possibility of recruitment of peer reviewers beyond those associated with the specific university with which DEP would contract for that work.

A member of the full SAB noted the need for a strong conflict of interest statement for the peer reviewers, and a strong freedom-from-coercion policy for those orchestrating the peer review process. In addition, the SAB member noted that a key to a credible process is to ask reviewers to declare their affiliations and interests when submitting their reviews, and to ensure that the orchestrator of the peer review process seeks a balance of interests across the reviews

<u>Charge Question #2</u> - Please comment on whether the options for the peer review process provide appropriate flexibility considering the types of risk assessments that the Division of Science, Research and Environmental Health develops.

In general, the Committee agrees that the document provides appropriate flexibility for options for peer-review of DSREH assessments. However, in order for options 2 and 3 to actually provide the intended flexibility, funding would have to be available *a priori*. It is not clear to the Committee that

such funding has been committed or would necessarily be available. The Committee recommends that if Option 2 is to be utilized, DEP/DSREH should first set up an umbrella contract with a university that would provide a mechanism for the university to manage peer-reviews whether or not the university is called on to manage such peer-reviews during the life of the contract. Presumably, such a contract with a university could be set up without cost until the actual review work were needed. However, for Option 3, a similar contract and mechanism would need to be set up in advance with a private contractor, and it is assumed that a cost to DEP would be incurred for that activity alone.

A member of the full SAB suggested that the efficiency of the peer-review process could be increased by pre-approving members of a potential peer-review pool.

<u>Charge Question #3 - Given the differences in cost and timing for the different review options, from a technical perspective please comment on whether there is a clear hierarchy for which option(s) should be applied to which type of risk assessment document to be peer reviewed.</u>

The Committee is not recommending a clear hierarchy of peer review options because it believes that DSREH is in the best position to identify the most appropriate option for the specific instances as they occur in the future. Some issues which the Committee anticipates would affect option selection are availability of funding for contracted reviewers (Options 2 and 3) and timely availability of university faculty (Option 2). Overall, the Committee suggests that the simplest options appropriate be utilized, beginning with a default use of Option 1 whenever it is appropriate and feasible for DSREH to identify and select volunteer reviewers.