

DRAFT EXTERNAL PEER REVIEW CHARGE
May, 2008

**Charge to External Reviewers for the
IRIS Toxicological Review of Beryllium**

The U.S. Environmental Protection Agency (EPA) is seeking an external peer review of the scientific basis supporting the human health assessment of beryllium that will appear on the Agency's online database, the Integrated Risk Information System (IRIS). There is currently an assessment on the IRIS database for the health effects associated with beryllium exposure.

The assessment for beryllium currently on the IRIS database was completed in 1998. However, the development of an Inhalation Unit Risk (IUR) for cancer was deferred until publication of a NIOSH epidemiologic study, subsequently published as Sanderson et al. (2001a). This draft assessment contains the updated cancer assessment. The derivations of the Reference Dose (RfD) and Reference Concentration (RfC) are unchanged and are not subjects of this review. The text associated with the updated cancer assessment, which is the subject of this review, is highlighted. Note that no changes have been made to the IUR for cancer, however, and the existing IUR has been retained

Peer review of the updated sections of this assessment is being sought to ensure that all available data relevant to the qualitative descriptor of the cancer assessment of beryllium have been appropriately and objectively evaluated. Below is a set of charge questions that address scientific issues in the cancer assessment of beryllium. Please provide detailed explanations for responses to the charge questions.

General Charge Questions:

1. Are the updated sections of the Toxicological Review logical, clear and concise? Has EPA accurately, clearly and objectively represented and synthesized the scientific evidence for cancer hazard?
2. Please identify any additional studies that should be considered in the assessment of the cancer health effects of beryllium.
3. Please discuss research that you think would be likely to reduce uncertainty in future assessments of beryllium.

Chemical-Specific Charge Questions:

1. Under the EPA's 2005 *Guidelines for carcinogen risk assessment* (www.epa.gov/iris/backgr-d.htm) (Section 2.5), beryllium via inhalation exposure is classified along a continuum between *likely to be carcinogenic to humans* and

carcinogenic to humans. Please comment on the scientific justification for the cancer weight of the evidence characterization for this exposure route. Has the scientific justification for the weight of evidence characterization been sufficiently, transparently and objectively described?

2. EPA has determined that the literature published since the 1998 IRIS assessment is inadequate to support a reassessment of the cancer inhalation unit risk (please refer to Appendix C of draft assessment). Please comment on EPA's rationale for not deriving an updated inhalation unit risk. Please identify any currently available studies or methodologies that could be used to derive an inhalation unit risk. Please comment on EPA's decision to retain the current IUR values..
3. Given that EPA was not able to update the inhalation unit risk factor and that NIOSH is in the process of updating its cohort analysis (both extending the follow up time by 13 years and adding two facilities with more recent exposure levels) that should prove valuable in updating the IUR, do you recommend placing the update of this Toxicological Review on hold until these data have been incorporated?