

DRAFT ABRWH COMMENTS

NIOSH STATEMENT OF POLICY: CONFLICT OF INTEREST

JULY 18, 2006 DRAFT

The ABRWH has reviewed the most recent draft of the Conflict of Interest policy. In general, we support NIOSH's efforts to improve and clarify the conflict of interest policy for this program and believe that it will improve the credibility of the program once this policy is implemented. The Board has several comments addressing our continuing concerns about certain issues that are not yet clearly spelled out in the most recent draft:

1. Footnote #2 – Page 1 – the definition of “conflict of interest” should include the “appearance” or “perception” of a conflict of interest (i.e., this policy should be trying to avoid or minimize actions that would have “the appearance of a conflict of interest”.) We do not believe that the use of the term “potential” conflict of interest fully addresses this concept. We suggest adding the following sentences to Footnote 2 “In some cases there may be an appearance of or perceived conflict of interest even where no legal conflict of interest exists. To the extent feasible, NIOSH will seek to minimize the appearance of or perception of conflicts of interest.”
2. Section 2.0 – Exception 2.1 – While we agree with the need to have a separate COI policy for the Board, we do not agree that the Board should “create and administer” its own policy, at least not independent of the COI provisions from FACA and other federal statutes that currently apply to the Board. The Board could supplement those requirements with additional requirements not in conflict with the FACA and other requirements currently in place. The Board does support the three COI provisions covering the Board's activities that are described in Appendix I. The Board recommends that discussion of this issue be placed on the agenda for a future Board meeting.
3. Section 2.0 – Exception 2.2 – The same concept would apply to the Board's current policy for our contractor. Federal procurement and other statutes have COI requirements for our contractor, and these have already been supplemented in the awarding of their contract. At the time, those requirements were generally more stringent than the ones in place for NIOSH's dose reconstruction contractors. The Board recommends that these requirements be reviewed at a future Board meeting.
4. Section 3.0 – The application of this policy to corporate entities is not clear. Although the introduction to Section 3 references both individual and corporate disclosure and exclusion, the subsequent sections (3.1, etc.) are confusing and often only appear to reference individuals not corporations. Corporate conflict of interest provisions are important, and this section should be modified to more clearly address corporate COI issues.

5. Section 3.0 – There is also some inconsistency in the reference as to whether AWE work is included in some provisions of this section.
6. Section 4.0 – There should be a corporate disclosure form in addition to the one for individuals (Appendix II)
7. Section 4.0 – The disclosure form for individuals should include a listing of the litigation cases that they participated in not just the relationship with the attorney. The listing of specific cases is common practice for expert witnesses.
8. Section 4.0 – The disclosure forms should be updated “within 7 days” or some other specific time period rather than leaving that open ended.
9. Section 5.5 – Portraying a site profile document owner as a “writer/editor” rather than as the “author” appears to downgrade the owner to a more passive role in the process. This person should not be just assembling sections written by site experts, etc. without critical review. As we have pointed out before, this is the weak link in this COI policy proposal to address the past practice of utilizing site experts who have an obvious potential conflict of interest as major contributors to a document. This new description of the “owner’s” responsibilities does not help convince the Board that this person will actively and fairly manage the process. This concern also applies to owners of other types of documents described in this proposed policy.
10. Section 6.4 – The designation of the Complex-Wide Technical Information Bulletin Owner as a non-key program function is problematic without a clear definition of this type of document. For example, this type of TIB may apply to only a few sites, and the “owner” of such a document should not be allowed to have the potential for a conflict of interest at one of these few sites.
11. Section 7.2 – We question the need for redaction of information on Corporate COI forms. This should at least be limited to specific types of information. An overly broad interpretation could undermine the credibility of this disclosure.