

Miller, Diane M. (CDC/NIOSH/EID)

From: Ellison, Chris (CDC/NIOSH/OD)
Sent: Thursday, March 03, 2011 7:25 AM
To: NIOSH Docket Office (CDC)
Subject: FW: Comments on "Quality of Science: A report of the ten year review of the NIOSH radiation dose reconstruction program"
Attachments: Comments on NIOSH Quality of Science Review.doc

Attached are comments on Docket 194 received by Ted Katz. Please post to the 194 docket.

Thanks!
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-----Original Message-----

From: Katz, Ted (CDC/NIOSH/OD)
Sent: Wednesday, March 02, 2011 12:07 PM
To: Wade, Lewis (CDC/NIOSH/OD) (CTR); Ellison, Chris (CDC/NIOSH/OD)
Cc: 'David Richardson'
Subject: FW: Comments on "Quality of Science: A report of the ten year review of the NIOSH radiation dose reconstruction program"

Chris -- Would you please send these comments from Dr. Richardson to the docket as well. Much thanks, --Ted

-----Original Message-----

From: Richardson, David B [<mailto:david.richardson@unc.edu>]
Sent: Friday, February 25, 2011 8:39 AM
To: Katz, Ted (CDC/NIOSH/OD)
Subject: Comments on "Quality of Science: A report of the ten year review of the NIOSH radiation dose reconstruction program"

Ted,

Could you forward these to Dr. Wade, if he is the appropriate person to receive comments on Draft Quality of Science Report.

David

Comments on "Quality of Science: A report of the ten year review of the NIOSH radiation dose reconstruction program" by David Richardson

Draft for public comment 2/14/2011

Major comments:

A considerable amount of work has been accomplished by the National Institute for Occupational Safety and Health (NIOSH) in support of EEOICPA; the NIOSH Director commissioned a ten year retrospective review of NIOSH's efforts. The current draft of this document focuses solely upon the quality of science related to NIOSH's work on radiation dose reconstruction. What has not been addressed by this review regards the substantial work undertaken by NIOSH in development of NIOSH-IREP and the scientific decisions and risk estimates that underpin the calculations that use dose estimates as inputs for deriving POC. I recommend that NIOSH take this 10 year review as an opportunity to review the quality of science for the entire scope of work undertaken by DCAS, rather than simply the program activities related to dose reconstruction.

The review of quality of science as it relates to the NIOSH radiation dose reconstruction program, however, is extremely thoughtful and well presented. The empirical example evaluating the DCAS approach is useful. Given the observation that an estimation approach that used co-worker data stratified by job, or department, and year would be more consistent with approaches used in epidemiological analyses suggests that another useful comparison would be to consider a data example where dosimetry and employment information is available by year and location, and compare the NIOSH co-worker model to the values derived using a model that was more highly stratified by covariates. Illustrative data might be derived for ORNL, SRS, or Hanford where epidemiological analyses provide such exposure and work history data.

Minor comments:

In several places through the document it is stated that dose reconstruction must be timely, valid, and precise (page 1), as well as fair and claimant-favorable, and in some places the term 'accurate' is included in this list (page 1). Not all of these terms are well defined, and no where are they explicitly defined. If these are the metrics upon which the final work product is to be judged, it would be helpful. Is validity the same as accurate, for example?

Page 8 “We also acknowledge that recent emphasis on validation methods in epidemiologic studies are most likely a direct consequence of the weak associations ...” I would argue that it is not a consequence of the magnitude of association (or exposure) but rather a consequence of a shift in study aims from hazard identification to quantification of risk. Regardless of magnitude of association, one wishes to have accurate exposure estimates (hence focus on these issues when considering transport of exposure information in studies of radiation doses from radiotherapy, for example).

Page 8 “Uncertainty in the exposure to an individual or even a group of individuals is likely to have little effect on estimates of relative risk provided the sources of uncertainty are not differentially associated with the outcome under study.” This is an overly broad statement (and probably generally incorrect). Classical measurement error certainly is a source of attenuation bias and occurs even in settings where the measurement error is not differential with respect to the outcome.

Page 8 Summary “...we find that methods of indirect exposure assessment in DCAS coworker analyses are consistent with those used previously in published studies.” I found one of the key insights in this section of the review (which was very thoughtful) was that most published occupational studies tend to employ much more stratified JEMs, defined by factors such as job, location and time, than the co-worker models used by NIOSH DCAS. I would suggest the above sentence be revised to reflect that the approach is ‘consistent’, but perhaps better described as ‘weaker’ or ‘less refined’. For example “we find that methods of indirect exposure assessment in DCAS coworker analyses are less refined than those used previously in published studies.” The fact is that a contemporary epidemiological study would be criticized if workers were simply assigned the annual mean exposure score for all workers at the plant in a year.