Hornung

Neton, Jim

From: Hornung, Richard (HORNUNRW) [HORNUNRW@UCMAIL.UC.EDU]
Sent: Friday, December 07, 2001 11:10 AM
To: Jim Neton (E-mail); 'ije1@cdc.gov'
Subject: Review of IREP document

Review of NIOSH doc.(1).doc

Larry/Jim

I am attaching my review of the IREP document. In general, I found it to be a very good description of IREP software. I had a few concerns that you will see in the review, some of which may not be on target since I wasn't sure if you wanted only comments on the documentation of IREP or also the assumptions that went into putting it together. The main thing that I think could improve it is a detailed example of how a typical claim's data would be handled—including which sources of uncertainty can be considered.

Please call me if you have any questions.

Thanks, Rick <<Review of NIOSH doc.(1).doc>>

Review of NIOSH IREP (ver. 4.0b) Technical Documentation

Thank you for the opportunity to review this document. It is not entirely clear to me whether you only require comments on the documentation itself or the methodology used therein. Accordingly I will provide several comments on both issues.

My primary comment concerns the purpose and potential audience for this document. One of the primary improvements in the use of the IREP software over the 1985 radio-epidemiological tables is the ability to account for uncertainty in information used to calculate probability of causation. However, very little is mentioned in the document about which sources of uncertainty are considered by IREP and how they are implemented by the software. It would be very beneficial to the reader to provide a more comprehensive description of how IREP addresses uncertainty. If possible, the inclusion of a typical scenario (similar to that shown in Appendix I but with more detail) for a claimant could be included as an example. This would include going through the steps in arriving at PC for a specific cancer type using the actual data values for that person. This description should also mention which sources of uncertainty are not addressed. The descriptions of the process should be tailored to the potential audience for which it is intended.

My next comment concerns the definition of GSD as found on pages 9 and 15. The GSD is estimated by calculating the half-width of the 95% confidence interval for the ERR and dividing by 1.96. Since the confidence interval was originally computed using the <u>standard error</u> (not the standard deviation) of the ERR, which is a function of the sample size, this estimate of the GSD depends almost entirely on one study (Pierce, et al 1996). This may be acceptable if this study is considered the definitive estimate for bone cancer risk. The same argument holds for skin cancer on page 15. This point should be made in the text. Also, it is not clear from the text how the GSD will be used. Is this part of the uncertainty calculation?

Table 5 is similar to Table 2, but includes the risk model to be used for each primary neoplasm. This is very important information, but requires the reader to search elsewhere for a description of each cancer risk model. It might be valuable to include an appendix that described each of the risk models and their source. At the very least, Table 5 should be footnoted to direct the reader to the appropriate reference(s) for this information.

On page 3, the document states that the revised version of IREP includes a lung cancer model developed in 1996 by the RECA Committee from uranium miner data. This is a much better approach than using atomic bomb survivor risk estimates for low LET radiation and then applying RBE factors. However, Table 7 lists an RBE factor for alpha particles. Is this RBE for alpha to be used only for exposures to such radionuclides as plutonium or uranium? If so, you may want to footnote this at the bottom of Table 7.

On pages 6 - 9, an extensive discussion of bone cancer is given with numerous citations from the literature. However, I saw no references to the radium dial painters. Is this because radium exposures are not considered by the legislation? There were radium- contaminated agents at Fernald, for example. Perhaps references to the dial painter literature should be added or reasons given for their omission.

There are many tables addressing the types of cancer outcomes and affected organs, but only Table 1 mentions exposures. This is a generic treatment of exposures to particular types of radiation (electron, photon, neutron, etc). Could a list of exposures encountered at DOE sites be developed by type of radionuclide? This might be useful to inform the reader as to the types of radionuclides found at DOE facilities and to list the type of radiation each of them can produce. For example, radon not only produces alpha radiation, but gamma and beta as well.

This naturally leads to my last comment on structure and policy issues in the document. I did not find any detail on how multiple exposures to different radionuclides or radiation types will be handled. On page 5, the document indicates that doses will be calculated to any affected organ. It is not clear how this will be done for different radiation types. For example, if someone with lung cancer makes a claim with exposure to radon as well as some form of gamma radiation, how will the lung dose be calculated? The document indicates that exposure to radon decay products will be measured in WLM, which does not lend itself to any precise lung dose without knowing a host of other factors. Some additional details regarding multiple exposures and types of radiation would be valuable.

My last few comments do not address the IREP structure per se, but relate to some of the assumptions that underlie it.

Table 6 seems to indicate that smoking will only be considered for lung cancer cases. Although lung cancer is the most common cancer associated with cigarette smoking, it is well-established that several other cancers are related to smoking. For example, cancers of the bladder, larynx, pharynx, and pancreas have all been shown to be related to smoking. It seems unfair to single out only lung cancer cases.

Some of the cancers on the list are not considered to be radiogenic and/or there has been very little research relating radiation exposure to their incidence. Given that a wider uncertainty interval could make the 99% percentile much higher than the point estimate for PC, how will this affect compensation? Will claims for these types of cancers actually be more likely to be awarded than those for well-known radiogenic cancers? You probably already considered this, but I felt the need to mention my concern.

A statement is made on page 14 that skin doses are well-estimated in the A-bomb survivors studies. I cannot imagine why skin dose estimates were better than other doses estimated in the Japanese studies. Perhaps a comment could be added to the document regarding this issue.

The inverse dose-rate effect for radon exposures is not considered by IREP. The principal reason given is that the miners studies do not observe this

effect below about 50 WLM. However, most studies, including those cited, find this effect at higher cumulative levels. Since preliminary estimates suggest that some Fernald workers, and possibly workers at other facilities, may be exposed to cumulative totals considerably above 50 WLM, the decision to ignore the inverse dose-rate effect may be premature.

If you have questions concerning any of my comments, please contact me at 558-2767.

Sincerely,

Richard W. Hornung, DrPH