Risk Assessment Corporation

May 7, 2001

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Dear Larry:

Thank you for your letter of April 18, asking about my ideas for implementation of the Occupational Illness Compensation Act of 2000 and Executive Order 13170. I appreciate your asking and will try to convey a few initial thoughts on this.

As I have mentioned previously, it would be worthwhile for NIOSH to look at the process and procedures being used for compensation of the veterans exposed during atomic bomb testing. I served on a National Academy of Sciences committee that looked into using dosimetry information collected on the veterans for epidemiological purposes. Our conclusion was that this dosimetry could not be used for a number of reasons. Among them were the lack in consistency in the methodology used and the failure to adequately account for uncertainties. My experience on the Academy committee was very enlightening and pointed out a number of mistakes we seem to be making with regard to dosimetry. Although the dosimetry information collected over nearly 20 years was not intended to be used for epidemiology, it still seems prudent that we should have considered this possibility in the compensation program. Nevertheless, there are a number of issues that I will pass along briefly. These are listed below.

- 1. Development of a defensible methodology for dose reconstruction. The foundation for any compensation program must be based on a defensible methodology. This methodology must include the latest scientific techniques for calculating doses and uncertainties and must include thorough consideration for all historical records. The best approach for doing this is to start with one facility that might best represent the different facilities included in the program. Use this location as the model for the methodology and expand the methodology to other sites. Starting small, developing the correct technical methods, then expanding the scale is critical to success. This will take time and resources but is worth it.
- 2. Develop dosimetry that can be used for epidemiological studies. As you determine your technical approach for calculating doses, be sure to assume they may need to be included in an epidemiological study. By making this assumption, you serve two purposes. First, workers will get a good estimate of their exposure and dose (and ultimately probability of causation). Second, we have crucial data that can be used in an epidemiological study to help us better understand the risk.

- 3. Be consistent in the dose assignment process. Once a good methodology is established, be consistent in how it is applied. This issue is of great importance, not only to the workers who may have been exposed but also in the value of the data in the future. Should new methods become available, and the methodology require updating, the entire set of records should be reevaluated to account for changes. Although this may seem difficult, it is not if the methodology is designed correctly from the beginning.
- 4. Decide early on how uncertainties will be handled. It is imperative that in estimating doses, uncertainties must be addressed. Uncertainty analysis is a quantitative process and must be handled as such for each dose calculated. As part of this issue, you must also decide the level of confidence you wish to use as the basis for compensation. I suggest something like the 95th percentile, but this is a technical and a policy decision.
- 5. Include the workers from the beginning in the design and implementation of the process. Again, a critical component of success. It would be a huge mistake to develop the process for compensation with the workers being included in the design of the methodology and also playing a role in its implementation. On the other hand, I strongly urge you to clearly establish the groundrules for worker involvement at the beginning so everyone knows what is expected of them.
- 6. Incorporate peer review. Be sure to include a strong peer review team for the development of the methodology and for implementation of the program. Use of the National Academy of Sciences or some other independent body is strongly recommended. By doing this from the beginning, it you will avoid criticism later on that could lead to bring in reviewers when the program is already underway and changes would be very costly.

These are just a few of the most important things to look out for. Above all, I suggest you get help in the historical dose reconstruction area to develop a methodology and see that the technical approach is laid out correctly. Not doing this from the beginning could be devastating to your plan and your overall success. There is no question that this science has evolved tremendously over the past decade and you must take advantage of what we have learned.

I hope these ideas will be useful. Each topic above is almost a course in itself and I apologize for not having the time to say more. I am sure you will do a great job with the program and wish you success.

Sincerely

John E. Till, Ph.D. President