Applicability of Radiation Response Models to Low Dose Protection Standards
Red Lion Inn
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Sponsored by

American Nuclear Society **Health Physics Society**

Overview

It is important to summarize the meeting to capture some of the important points made and outline the present so that we can prepare a path forward based on the results of the meeting. We had the whole meeting put on tape. This along with publication of the extended abstracts and a summary of the meeting will help document the meeting. Additional information is available since a number of the scientists and regulators present were interviewed and these will also be available. What follows is a summary of the meeting which the hope of carefully documenting all the information without a preconceived notion of where the meeting would take us or what the conclusions would be.

Without funding this meeting would not have been possible. We appreciate all those that worked to get the funding and the agencies that made the generous contributions to make the meeting possible. We were able to provide travel money for many that would not have been able to attend without this help. The food, tours and activities that made the meeting a pleasant experience was also a direct result of funding. A list of those that contributed is available on the program.

This meeting was almost four years in the making with Dr. Alan Walter as the Chairman for the meeting. We put together an excellent international advisory council (IAC) which helped us attract scientists from around the world. The organizing committee invested many hours in planning, organizing the meeting and obtaining funding for the meeting. Both the international advisory council and the organizing committee are listed in the program.

The program for this important meeting is attached which shows not only the presenters but also those that sponsored the special events. Also attached are the poster presentations with the authors, title and poster assignment.

Meeting Introduction

To start the meeting Dr. Alan Waltar and Dr. Mike Lawrence provided a path that they hoped the meeting would follow. Several specific goals for the meeting were developed and presented by Dr. Mike Lawrence which laid the groundwork for what followed.

1) Explore the current scientific knowledge and understanding of low-dose radiation effects.

2) Consider the applicability of this knowledge as the scientific foundation for current radiation protection standards, and

3) Recommend a path forward.

It was not the intent of this conference to assume the responsibility for the political side of standard setting , but it was our goal to reach consensus on as many important questions related to the dose-response relationships and to use this information to impact potential regulations. The scientific evidence of harmful human effects of exposure to radiation in the high dose region is well defined from data derived from large exposed human populations. However, the data from human populations is limited in the very low dose region. We must challenge the concept that it is possible to evaluate precise risk estimates due to low-level radiation given our wide range of natural background radiation and the high incidence of cancer from all causes combined—both natural and those arising from human activities. We might therefore ask, and, hopefully, reach consensus on what is the lowest level at which we can definitively assess risk, and to what degree it makes sense to regulate at levels below those levels.

Dr. Alan Waltar the program chairman instructed those participating to be considerate of others and limit their presentations to the time allotted. He asked them to consider the four following points and after the completion of the meeting we feel that those participating in the meeting were successful in doing this.

1) Be a strong advocate for your position; that is why you are here.

2) By all means, present additional facts; not alternative facts.

3) Be open to new information; listen and consider how different data and analysis applies to our goals and be open to someone else's "facts".

4) Apply the scientific method to help us achieve our goal: observe, experiment, measure, and evaluate.

Summary

In this summary, we will not attempt to include all the information presented by each and every person in the meeting. All this information is available in a video form as well as extended abstracts will be published in the Health Physics Journal. Here we focus on general themes provided from the presentation, panels and posters with emphasis on areas where we could reach some type of consensus as well as those where diverse opinions still exist. We had a total of 46 presentations in the meeting and 7 panels where we included an additional opportunity for participation from all those registered in the meeting. Each of the panels resulted in active discussion and after panel we had to limit the discussion because of lack of time. The discussions were dynamic but we were able to maintain a continued good order and interaction between those with very different opinions. We had a total of 42 scientists that requested space

for posters but not all of them were able to attend and make a presentation. A listing of the poster session are also attached to this summary.

It was the hope of the organizing committee that we could get a wide range of different scientists, regulators and stake holders together and after the meeting reach consensus on important issues. This consensus could then be carried forward to provide input for future decisions regarding the use and regulation of radiation exposure. There were several areas where consensus seemed to be reached. We will survey the participants to determine the degree of agreement on important issues.

However, It was obvious that there were areas where consensus was not possible, such as the shape and slope of the dose response relationship in the low dose region. Dr. Ludwig Feinendegen provided his overview of the meeting which follows. There is very little question that the meeting reached its goal. The goal of open exchanges of facts, views, interpretations, hypotheses and theories and of their consequences of optimization of radiation protection with the best possible outcome in the service of society. Extensive efforts were made to ensure that the interdisciplinary composition of the experts was well balanced and came from a wide range of backgrounds including epidemiology, systems biology, cell and molecular biology, biochemistry, biophysics, health physics, mathematics, model makers, legal socio-economists, physicians, decision makers, administrators as well as having lay people directly impacted by decisions to evacuate. After three days of meeting with this high-powered group it became obvious that there were several areas where we were able to almost reach consensus. However, there are several other areas where serious differences remain. These are listed below, and extensive discussion and data were presented by all sides of these controversies. The major differences seem to be related to the shape and slope of the dose-response relationships in the low dose and dose rate region of the dose response relationship for the induction of cancer. These can be easily divided into three easily distinguishable groups.

The first and oldest group holds the Linear No Threshold (LNT model) to be best model for the practice of radiation protection. This suggests that each and every ionization increases the risk of cancer and genetic effects regardless of the total dose. There are extensive data that suggest that this model is not scientifically supported. However, this group advocates the continued use of the LNT model for practical administrative and executive reasons since it seems to be conservative in protection of the public.

The second group suggests that the data support the fact that the health effects from low doses and low dose rates are well defined and negligibly small and that the LNT model be replaced by a threshold model. Doses below this threshold should be of no concern for the induction of health effects and to be declared as “safe”. The strength of this argument is twofold. First, there is lack of evidence of a detectable increase in human cancer incidence in the low dose region especially if delivered at a low dose rate. This observation is supported by a wide range of molecular, cellular and animal data. Radiation induced disease produced or calculated at these levels of exposure are very small even with the use of the LNT model. Second, we have exposed almost the whole world to low doses of radiation from fallout, nuclear medicine and use of radiation in industry without detectable levels of cancer increase. Thus, it is rather well accepted that the standards set using the LNT model are conservative and do not underestimate the risk and much data support the position that the LNT model is conservative and overestimates the risk.

The third group have been strengthened recently with the advance of research in cell and molecular biology that demonstrates that low doses of radiation increase the gene expression in a

different set of genes than those induced by high doses of radiation. Many of the genes activated by low doses of radiation have been postulated to be protective. The research also demonstrated that cell/cell and cell/tissue communication is stimulated by low doses of radiation that lead to stress response type of metabolic alterations which result in protection against radiation damage and adaptive protective responses. If the radiogenic damage prevention induced by the low dose exposure outweighs radiogenic damage then a decrease in the risk is produced and the overall system experiences a hormetic response. That is the amount of damage and risk induced by the radiation is reduced to a level that is lower than the spontaneous background level. Thus, modeling should include negative values in the low dose region. This group suggests that low doses of ionizing radiation may be essential to the evolution and maintenance of life.

With the differences carefully spelled out above, it is important to now view the areas which we as the organizing committee thought some type of consensus was reached.

First, it was the opinion of the group that the fear of radiation is a serious problem and lack of communication between the scientific community and stake holders seem to be a major contributor to that fear. This fear of radiation is far greater than the scientific data can justify since we have a large human data base of human where large populations were exposed to a wide variety of different scenarios. This human data base form the basis for our regulations and there is general agreement that in the high dose region these regulations are adequate and conservative. The radiation risk has not been underestimated since if it were large numbers of cancers would have been detected in humans exposed to low doses of radiation. This has not been the case. However, fear and concern that we have underestimated the risk is reinforced almost daily in the news media, the regulatory actions taken and laws that provide financial rewards to those who have received low doses of radiation. This fear has wide spread financial and societal impact and impacts decisions we make on a daily basis.

Second, there was general agreement that there is a need for carefully directed, focused research that can address regulatory concerns. With scientists from around the world at this conference it became obvious that further information is needed which can be derived from further well directed scientific studies can have impact on regulations in the future. This research needs to be adequately funded and be international in nature. The research must be directed toward linking molecular biology to human epidemiology so the uncertainty associated with human risk or benefit from low doses of radiation can be carefully defined. Such research can pay serious dividends in understanding the risk of low doses of ionizing radiation in humans and provide a basis to address fear.

Third, it seemed to be a consensus of those in the audience that the standards for public exposure set at 1 mSv per year are excessively restrictive. Since the natural background level of radiation is 3 mSv/year (there are areas where the background is 100 times higher) and medical exposure adds an additional 3 mSv. There is little we can do to alter background radiation and it is not scientifically sound to regulate exposures in the range of natural background. If we could alter the standard for public exposure from 1 mSv/year to levels seen in natural background for example 5 mSv/year there would be no impact on public health, we could alter the fear of radiation and make our everyday decisions easier as we use radiation in whys to benefit mankind.

Similar discussions were very actively induced by the standard of 20 mSv/year set for evacuations of populations in the event of a nuclear accident or nuclear war. These discussions were for the most part based on the evacuations at Fukushima. This is a very small dose with no acute adverse health associated with it. Using the LNT model, with a risk value of 5%/Sv, it can

be seen that, even though there is disagreement as to the shape of the dose response relationship in this dose region and this may be at the upper end of risk, the calculated increase in cancer frequency at this dose is 0.1%. This has to be viewed in the light of the fact that about 40% of the population get cancer and 25% die from it. With the wide range of natural background cancer which in influenced by genetic background, cigarette smoking, diet and life style this increase could never be detected in a population with standard epidemiological methods. This dose for evacuation is less than half the dose that the downwinders in Southern Utah, Nevada and Arizona got from the fallout produced by the A-bomb testing in Nevada. Even though the dose in Southern Utah exceeded the value currently used for evacuation the cancer rate in Utah is the lowest in the nation and the cancer rate in Washington County which received the highest dose from the fallout is second lowest in the State of Utah. All this shows that evacuation at this exposure level has no impact on cancer and the social, economic and fear generated by the evacuation has very serious consequences as demonstrated at Fukushima.

Forth, the discussion on the use of radiation in medicine was evaluated and discussed. It was again the general consensus of the meeting that medical uses of radiation provide great benefit and one should not refuse a medical exposure if it is justified and recommended by the medical experts. The risk from medical exposures was carefully compared to some real data on the benefits associated with medical exposure. There was focus on the use of CT scans since a single CT scan delivers a dose of up to 10 mSv and we deliver over 90 million CT scans per year. The individual risk from this procedure is very small relative to the great benefit derived and the many lives saved each through the use of CT scans.

Path Forward

The path forward and the total impact of the meeting will be dependent on how well the information from this meeting is accepted, disseminated and incorporated into decisions related to the control of radiation exposures. We the organizing committee have made a commitment to continue to work with the collected data. It is the hope that this meeting will have a long-lasting impact on radiation biology and the regulations associated with protecting the public with adequate and appropriate radiation standards.