

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

TRIP REPORT

SUBJECT: Seminar: Analyzing Risk—Science, Assessment, and Management

DATE/PLACE: Boston, Massachusetts
April 10–13, 2007

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PERSONS PRESENT:

Approximately 50 international participants (primarily United States and Canada) attended the course.

BACKGROUND AND PURPOSE OF TRIP:

The Harvard School of Public Health annually holds a short course entitled Analyzing Risk: Science, Assessment and Management. The course covers the fundamentals of risk analysis and decisionmaking, including techniques for determining risk, cost-benefit analysis, and consideration of regulatory implications of risk analysis. The CNWRA staff attended this meeting to enhance our risk assessment and communications abilities, particularly in the area of Public Outreach and other stakeholder interactions. M. Juckett attended this course for training as Principal Investigator for Public Outreach.

SUMMARY OF PERTINENT POINTS/ISSUES:

The course was held over 3 ½ days with several speakers giving lectures. Topics included basics of risk assessment, exposure assessment, toxicology and epidemiology for risk assessment, analysis of variability and uncertainty, benefit-cost analysis, risk perception, and communication.

Dr. John Evans of the Harvard School of Public Health discussed Risk Assessment—the process by which risks are examined so as to illuminate judgments and assist in decisionmaking. The results of risk assessments are usually in the form of probabilities, and these results are best communicated as comparisons to commonplace situations. The four elements of risk assessment are hazard identification, exposure assessment, dose-response assessment, and risk characterization.

Dr. Jonathan Levy of the Harvard School of Public Health discussed Exposure Assessment, which is the process of measuring or estimating the human exposure (intensity, frequency, or duration) to an agent present in the environment or estimating a potential risk that may occur. Both measurements and models can be used in exposure assessment. Exposure can be measured directly and may consider microenvironments, which are concentrated areas of exposure. Biomonitoring is considered a good method for elucidating mechanisms of exposure

but is difficult to tie to a specific source. Where monitoring is not possible, modeling can assist in estimating exposures, though it is reliant on a wide variety of assumptions. Dose calculations were also discussed, including potential dose, applied dose, internal dose, delivered dose, and biologically effective dose.

Dr. Wallace Hays of the Harvard School of Public Health gave a presentation on Toxicology for Risk Analysis. Toxicology is a study of the adverse responses in biological systems caused by chemical or physical agents. He particularly emphasized that dose is important, as in the case of botulinum toxin or various biologically necessary minerals. Duration and frequency of exposure, as well as route of administration, also affect toxicological effects. Susceptibility varies among individuals. Pharmacokinetics describe the absorption and distribution of the toxin throughout the body and affect the biotransformation of the toxin into usable or excretable forms. Species and size are major factors in toxicology, thus presenting the challenge of interspecies extrapolations in animal testing.

Dr. Joel Schwartz, also of the Harvard School of Public Health, discussed Epidemiology for Risk Assessment. Epidemiology is the study of health effects throughout a given population from a given source. It is a difficult study due to the range of exposures and differences among individuals in a population. Models can assist in extrapolation across species, but intraspecies variations make it an inexact science. Most epidemiological studies include threshold values where dose response is measured against effects. Confounding effects are also important considerations in epidemiological studies (e.g., the synergistic effects of two toxins or the dependence on one effect based on another effect).

Dr. Joshua Cohen of the Tufts-New England Medical Center discussed Analysis of Variability and Uncertainty. He discussed the necessity of larger and representative samples to ensure a more accurate distribution of results, as demonstrated by Monte Carlo simulations. Variability refers to differences among members of the population that result in the heterogeneous distribution of risks, while uncertainty refers to the availability of alternative plausible assumptions, and each implies a different estimate of risk. These two factors are important for decisionmaking because the decisionmaker must determine whether the results of a study are sufficient to warrant action and what portion of a population (based on distribution) the action should cover.

Dr. James Hammitt of the Harvard School of Public Health gave a presentation on Benefit-Cost Analysis which measures allocative efficiency. The goal is to reach the greatest good summed over the population. Other important criteria include procedural fairness, feasibility, fundamental rights, constraints on choice, and distribution across a population. Some actions are viewed as unnecessary because the benefit would not outweigh the risk or be detectable against the background. Benefit-cost analysis is important because small benefits can be worth buying if the cost is small enough, and large benefits may not be worth buying if the cost is too large.

CONCLUSIONS:

The course was beneficial and informative.

PROBLEMS ENCOUNTERED:

None.

PENDING ACTIONS:

None.

RECOMMENDATIONS:

This course would be beneficial for any staff involved in risk assessments, public outreach, or stakeholder interactions.