BRIDGING RADIATION POLICY AND SCIENCE

An International Conference
Airlie House Conference Center, Warrenton, VA
1–5 December 1999

Kenneth L. Mossman, E. Gail de Planque, Marvin Goldman, Kenneth R. Kase,
Sigurdur M. Magnusson, L. Manning Muntzing, and Genevieve S. Roessler

INTRODUCTION

Overview

Natural and man-made sources of ionizing radiation[1] have made and continue to make invaluable contributions to society and to individuals. Radiation is part of nature. Natural sources of radiation including radon gas from the earth's crust and cosmic radiation from outer space account for 80-90 percent of the radiation to which the public is exposed every year. Man-made sources provide hundreds of beneficial uses including medical and dental x rays, nuclear medicine pharmaceuticals, and nuclear power plants. Man-made radiation, used primarily in medical diagnosis and therapy, accounts for 10-20 percent of the public's exposure every year.

Individual and population exposures to man-made radiation sources are controlled so as to minimize potential detrimental health effects (primarily cancer) without compromising the beneficial uses of radiation. The selection of appropriate levels of control of radiation exposures is a complex matter. The issue is especially problematic because cancer occurs at high rates in the general population and it is almost impossible to detect small excess cancer risks attributable to low levels of radiation exposure. Public exposure limits have been set at levels orders of magnitude below exposure levels known to cause cancer. Regulations to limit environmental and occupational exposures to radiation are based on the assumption that any dose of radiation, no matter how small, may cause cancer. While regulatory decision-making was designed to protect the public health, in some ways it has become punitive and burdensome. The idea that any exposure to radiation may be harmful has led to public anxiety and to enormous economic expenditures that are disproportionate to the actual radiation risks involved. In the United States and some other countries, regulatory compliance costs are steadily growing while desired public health benefits from added regulation are increasingly difficult to measure.

Conference Goals

"Bridging Radiation Policy and Science" was an international conference held at the Airlie Center, Warrenton, VA 1-5 December 1999. The conference brought together by invitation 78 engineers, lawyers, policy makers, regulators, scientists, and psychologists and other social scientists from around the world in an attempt to reach a consensus among people who have taken different technical, and policy and regulatory positions on the important societal issue of low-level ionizing radiation exposures. A list of participants is provided in Appendix A.

The conference provided a forum for international participants to share personal and national views on a wide variety of policy, regulatory, scientific, ethical, economic, psychological, science, and policy questions pertaining to low-level radiation health effects. The conference facilitated a rich international dialogue that promises to be of great value to policy makers, regulators, and scientists interested in developing appropriate public policy with respect to exposure to low-level radiation.

The goal of the conference was to develop strategies for formulating national and international policy based on current scientific information in the context of economic, political, and social concerns. Specifically, the conference attendees explored how to establish public policies (legislation, regulation, etc.) with respect to radiation protection in view of the scientific uncertainties of the effects of low-level radiation [<100 millisieverts (mSv)].

Format of the Conference

[1] Ionizing radiation includes x rays and gamma rays. They differ from other types of radiation such as visible light, ultraviolet rays, and ultrasound by their ability to cause ionization of atoms and to break chemical bonds.

Prior to the conference invited participants were requested to submit a 1-2 page statement concerning what they considered to be the major issues of the conference and their expectations regarding the outcome of the conference. A conference briefing book containing all statements was distributed to the participants about one week prior to the meeting. The briefing book served two purposes: First, it gave each participant an opportunity to review issues about which others were concerned. Second, the organizers used the briefing book to develop discussion questions that were critical to the organization and outcome of breakout sessions.

The conference was organized to promote the exchange of information and discussion among the participants. This was done through plenary and breakout group sessions. The technical program is provided in Appendix B. Facilitators who did not have a professional interest in the subject material led plenum and breakout group discussions. After an opening session to set the conference goals and objectives, a policy session addressed the challenges in setting policy at the highest level and what the policy makers need to know. A sequence of sessions examined relevant issues, including scientific uncertainties; economic, political and social factors that influence policy; international organizations and policy; regional and national policy issues; and, issues bridging science and policy. Each session included keynote presentations providing brief overviews to set the stage and stimulate the discussion in plenum. The goal of the last plenary session was to finalize conference conclusions and recommendations. A summary of each session is included in this report. Three breakout sessions were scheduled during the conference to explore specific questions relevant to the goals of the conference. Each participant was assigned to one of four breakout groups. Group assignments were made to balance national and professional perspectives in each group. Each group considered the same set of questions. At the end of each breakout session, a group reporter summarized discussions in a plenary session.

The breakout questions were as follows:

Breakout I: Clarify/define the issues associated with balancing science and the other factors influencing policy

- What do policy makers and regulators need to know in order to make decisions?
- How do risk, economic, social, psychological, political, scientific, and ethical factors influence policy and regulations?

Breakout II: Develop recommendations on the formulation of policy and regulations

- What are the major scientific uncertainties of concern to policy makers and regulators and is it appropriate to use predictive theories to establish policy and regulations?
- How can advisory bodies (e.g., ICRP, NCRP) be used appropriately in the policy-making and regulatory process?
- How can constituency (e.g., public, industry) concerns be more effectively incorporated in the policy-making and regulatory processes?

Breakout III: Develop recommendations on the use of available resources, guidance on directions, and continue to develop overall recommendations and conclusions

- Are current regulations and policies appropriate? If not, what are the alternatives? What are the social and economic costs and benefits of alternatives?
- Should there be an international agreement to adopt a single coherent and consistent system of regulations and policies?

PLENARY SESSION SUMMARIES

Session 1: A Philosophical Overview of Policy Making

The first session of the conference focused on the challenges of setting policy and on what the policymakers need to know when formulating policy at the highest level. The description below reflects not so much a summary as the highlights of each person's remarks that indicate the needs of policy makers.

Peter Lyons began the session by reading a statement from U.S. Senator Pete Domenici who was not able to attend the session in person and sent his regrets. The Senator is keenly interested in the accuracy of the linear, non-threshold (LN-T) theory and commented that "If these standards overestimate risks, they force us to divert funds from other, potentially more worthy, national goals." Further, he was critical of the way the LN-T theory is being used, especially by the U.S. Environmental Protection Agency. He has personally taken action to influence the creation of an $18 million research fund for the Department of Energy to look into the effects of

low-level radiation. He has also instigated an investigation by the General Accounting Office to assess the cost impact of the application of the LN-T theory to projects such as the disposal of high and low-level waste, nuclear power plant decommissioning, and environmental cleanup, as well as to look at variations of levels of natural background radiation in the U.S. and any correlation with cancer incidence. Finally, he is considering having Congress "…mandate that no standards be more stringent than the variation in natural levels within the United States for any substance or phenomena, unless specific health studies support the need for a departure." The Senator's bottom line is that responsible and honest scientific information is needed to guide policy and that standard setters need to be mindful of costs.

Bennett Johnston expressed similar reservations. He is especially concerned about costs. He gave as an example the costs for site characterization of Yucca Mountain, originally estimated to be $60 million and now estimated to be $6 billion, all due to what he sees as standards that are unnecessarily stringent and unjustified by the scientific evidence. He also expressed concern about the extraordinary public fear of radiation and on the other hand, scientists who seem to want to be politicians and heroes of the public and the press and distort science in that attempt. Bennett Johnston's bottom line was that scientists and policy makers should follow good solid science.

Andrew Miller described guidelines set up by the British Government, setting out key principles for the presentation of scientific information for policy making. These guidelines address: the ability to identify issues early; the need to obtain information from a wide variety of sources; and the need to ensure that the process leading to a balanced view be transparent and consistent across policy areas. Miller emphasized the need for European Community policy to have a sound scientific basis. He recommended that scientists whose advice is being sought should help decision makers frame and assess policy options. Finally, he stressed the "…need to ensure that our citizens are well-informed and are not simply reliant upon the views of an editor with an ax to grind or of a pressure group."

Simon Carroll took a fundamental and philosophical approach. He stressed the importance of establishing the principles that should underpin policy and determining how they apply in practice. He stressed the need to identify what further scientific data needs to be collected to modify current policy or regulation. Carroll raised the question of how can reasonable decisions be made when there are uncertainties in the scientific data on the one hand and disputes on the underpinning principles on the other. He stressed the importance of the "precautionary principle" as a guiding principle in decision making in this field and emphasized that, while risk assessment was an essential component of the application of the precautionary principle, risk assessment should be seen as only one of a number of factors to be taken into account.

Junko Matsubara presented a very useful description of the recent accident at Tokai Mura, Japan, together with the reactions of the experts, regulators, government and the public. She stressed the need for experts and the public to arrive at a proper recognition of risk, cost, and benefit of nuclear technologies. She gave support to the idea of comparing dose limits with natural background levels as a way to convey a better sense of level of risk.

KunMo Chung pointed out the great needs of developing countries for nuclear technologies in securing clean energy and utilizing radioisotopes for medical, agricultural and industrial applications. Because of the uncertainties that exist surrounding the LN-T theory, he cautioned that the scientific community needs to convey flexibility in options to the policy makers and regulators. He emphasized the need for stakeholders participation in policy making along with the need to inform the public about "…unsubstantiated health effects and the existing uncertainties of scientific conclusions." He called for international collaboration on studies and recommendation and concluded that "We cannot afford public policy based on untested scientific judgement and illogical assessment of risks."

In summary, several key consistent messages can be distilled from Session I:

- underpinning principles should be established,
- policy should be based on sound science,
- uncertainties should be clearly delineated,
- processes need to be transparent,

- policies need to be consistent (nationally and internationally),
- stakeholder input is essential,
- citizens need to be accurately informed in language that is understandable
- relating dose limits to levels of natural background radiation and/or variations is useful

Session 2: Science Issues

In "The Science Issues" session, formal presentations and discussions on epidemiological and molecular and cellular radiobiology investigations focused on the nature of scientific uncertainties, and some of the current research problems and future needs to clarify mechanisms of radiogenic health effects, and to reduce uncertainties in low-level radiation risk estimates. In the context of bridging policy and science, this approach was considered to be more productive than to attempt to resolve the LN-T debate, and its related policy and regulatory implications.

Epidemiology

Shigenobu Nagataki provided an overview of the Radiation Effects Research Foundation (RERF) activities including the current status of the Life Span Study (LSS). This is the major source of data used by the scientific community to estimate the magnitude of radiation risks at low doses. The LSS was established in 1950 and has over 80,000 subjects. About 75% of the exposed individuals received radiation doses less than 100 mSv. The objective of the RERF is to provide long-term follow-up of the large cohort of A-bomb survivors; to consider all biologically plausible theories to describe the shape of the dose-response function; and to consider modifying factors such as age, that may affect the dose-response pattern. Although each scientist may analyze data according to his/her own ideas, hypotheses, or methodologies, RERF has to consider seriously all suggestions, proposals, and criticisms. In this regard, collaborations with RERF are welcomed. Nagataki provided the following summary concerning the LSS solid cancer data: (1) there is a statistically significant dose-response over the range of 0-200 mSv; (2) the slope of this response is consistent with, and virtually identical to that for the full dose range; and, (3) the best estimate of a threshold is essentially zero with an upper 95% confidence bound of less than 100 mSv. The understanding of cancer risks at low doses is limited, and thus a broad scientific approach including molecular and cellular radiobiology studies has to be considered. New molecular biology studies on the basic mechanisms by which radiation causes its effects can be conducted using the unique collection of tumor tissues from the RERF registries

Dale Preston and Charles Land discussed some of the major scientific issues and limitations in radiation epidemiology based on experiences related to the A-bomb survivor data. Preston identified some of the limitations of low-dose epidemiological studies including the low power (chance of detecting an effect when the effect is present) of studies in the low-dose range (less than 100 mSv), the difficulty and expense in conducting adequate medical follow-up of subjects, and the appropriateness of the study population as representative of the general population. He noted that the relevant hypotheses to be explored in epidemiological studies are: Does radiation modify disease risk?, and are the low dose risks consistent with linear extrapolation from risks seen at higher doses (the failure to observe an effect does not necessarily equate to no effect)? Preston outlined the strengths and limitations of several populations that provide or may eventually provide useful information on low-dose risks. These include the pooled analyses of nuclear worker cohorts, the Mayak and Techa River cohorts, Chernobyl liquidators, and the RERF LSS cohort. Preston also discussed issues in cellular radiobiology including radiation effects and cells, how such cell effects determine long-term disease risk, and protective mechanisms, noting that uncertainties about repair, epigenetic effects, adaptive response, etc. preclude definitive conclusions in the low-dose range.

Land focused on quantifying the level of statistical uncertainty in the atomic bomb survivor cohort using, as examples, breast cancer and pancreatic cancer. Another source of uncertainty, translating risk estimates derived from one population to another population with different demographic characteristics, was also discussed. Land also explored the issue of thresholds. Based on present evidence, it is not possible to postulate with certainty any threshold below which there is no risk. While a threshold cannot be totally ruled out, allowing for that possibility had little effect on the upper confidence or credibility limits for risk at low doses. Thus, the uncertain possibility of a low-dose threshold is unlikely to have any practical influence on a conservative, risk-based radiation protection policy.

Discussions on human health effects focused on the LSS data. Preston indicated that modification of Hiroshima neutron doses, while lowering the LSS-derived risk estimates somewhat, still appear to be consistent with low-dose linearity. It was also recognized that studies of residential radon exposures and lung cancer risks

and various medical studies have also been conducted and provide important epidemiological evidence that complement the LSS data. In addition, a large body of data derived from laboratory animal studies have been important in identifying various host and environmental factors and their relation with radiation as determinants of cancer risk. Studies in animals have also been important in bridging effects observed at the molecular and cellular level with the appearance of cancer in the whole organism.

Molecular and Cellular Radiobiology

Carmel Mothersill, Richard Setlow, and Klaus Trott reviewed the current status of molecular and cellular radiobiology, factors that modify risk, and what scientific studies may be useful in clarifying mechanisms of molecular and cellular damage, and how uncertainties in radiation risk may be reduced.

Mothersill reviewed effects of radiation on cells at low dose (less than 50 mSv) including genomic instability, persistence of stress response, bystander effects (field effects involving cells not hit by radiation), apoptosis (programmed cell death), proliferation stimuli and induced repair. Cell damage at low dose appears to be similar to stress response. Stress response is saturated at doses less than 10 mSv. The consequences of exposure are dictated by the response to the damage rather than the damage itself. There are important scientific questions that are still to be resolved: What are the mechanisms and consequences of genomic instability and bystander effects? How does a particular cell decide whether to repair radiation damage or induce apoptosis? Since some environmental agents (e.g. some metals) also produce genetic instability, are there common mechanisms involved in radiation and chemical injury? Understanding the long-term health impacts of radiation exposure requires a shift in thinking away from effects in single cells (such as DNA double strand breaks) to field effects and damage in cell populations and tissues and organs. Long-term effects in cells are becoming increasingly important. Tissue architecture and proliferation kinetics of stem cells and progenitor cells are important in understanding long-term disease processes. Mothersill also stressed that evidence for thresholds for specific mechanisms did not mean that thresholds exist for disease risk.

Setlow discussed factors that modify radiation risk at the cellular level: DNA repair removes damage before replication. Adaptation involves small doses of radiation that reduces the effects of subsequent large doses. Apoptosis reduces mutations and possibly cancer by programmed cell death of damaged cells. Bystander effects involve cells damaged by high linear energy transfer (LET) radiation (e.g., alpha particles) that may result in mutation and transformation of contiguous neighbors. Genetic instability involves chromosomal changes and mutations that may appear after a large number of cell divisions. Setlow also discussed the nature of DNA damage and its repair. Single strand breaks and base damage are repaired rapidly and completely. These DNA effects occur very frequently in cells but have little, if any, health consequences. Double strand breaks occur much less frequently (about 5% of the single strand break rate); the fact that the repair of such damage is slow and incomplete may have significant health consequences. The health consequences of multiply damage sites in DNA may be significant; repair of such damage appears to be inefficient. The kinetics of DNA damage in cells argue against the existence of a threshold.

Klaus Trott discussed several scientific issues that need to be addressed for future policy and regulatory decision-making. Low-dose epidemiological investigations are limited in part because of the non-specificity of radiogenic cancer and the absence of clearly distinguishable (DNA?) fingerprints to identify radiogenic disease. The molecular features of the specific mutations in radiogenic cancer in man (PTC 3 translocations or point mutations rather than deletions as was expected) suggest that the critical mutation does not occur as a direct result of radiation interactions with DNA but during processing and/or repair of the initial lesion. These observations do not support the microdosimetric argument in favor of the LN-T theory.

In the discussion, there was a consensus that no breakthrough exists that would have permitted a final conclusion about the shape of the dose-response at low doses. There were various questions about technical issues of particular analyses, but these did not affect the general conclusion about uncertainty. Some differences of opinion existed about the correct way to handle presumed but undetectable small risks-should they be disregarded or not?

Session 3: Bridging to Application-Factors that Influence Policy

This session summarized a number of factors other than science that impact policy and regulation. Presentations focused on risk, economic, social, psychological, and ethical factors.

Risk Assessment

George Gray made the case that, because of limitations on resources, comparative risks should be taken into account in setting priorities for resource allocation. This should apply to all societal activities, including the regulation of radiation exposure. The principles of risk analysis are becoming accepted and used beyond simple standard setting to risk management. It allows quantitative determination of benefit/cost ratios and allows society to expend resources on tackling the worst problems first. Risk analysis has been used to compare different types of risk and communicate these comparisons to the public. This has proved effective in helping prioritize risk in over 35 U.S. states, regions, and tribal governments.

In making comparative risk analyses it is important to use the best available information on risks and account for uncertainties, rather than to use conservative values. The latter have been justified on the basis that it is better to be safe than sorry, but conservative input can skew the results towards unrealistic comparisons. Precautionary notions do not belong in risk assessment exercises - this is a social factor that should be applied when the real risk is known. However, there is still much to be done, and evolution of risk analysis methods and risk characterization must continue if this technique is to fulfill its true potential in helping to guide policy makers and regulators towards optimal solutions for society.

Economics

Neville Chamberlain examined the economic cost of regulation. He used several examples to illustrate how meeting escalating regulatory requirements has driven costs to unreasonable levels for the benefits obtained. In particular, the collective dose concept has been inappropriately applied. Multiplication of very small individual doses by very large populations is an incorrect application and abuse of the collective dose concept as developed from the LN-T theory. If there is no agreement on a threshold for radiation-induced health risks, we must get the near-zero risks in proper perspective and agree on a cut-off level for regulatory purposes and restore a balance to the use of economic resources. The conclusion was that a line has to be drawn somewhere in the reduction of radiation dose at ever increasing costs. Chamberlain argued that the absence of such a line amounted to economic abuse of prudence and has resulted in a vacuum that has led to distorted energy policy. Clear guidance from the scientific community is needed to counter the trend of political campaigners and the popular media to use unscientific and emotional information to sway politicians and regulators towards requirements that result in unnecessary expenditures to the detriment of society at large.

Social Issues

In addressing social issues, Rick Jones proposed that the time has come for shared responsibility. We need more communication and transparency. Current and past U.S. practice have involved recommendations from national and international bodies using a closed group of professionals (where tradeoffs were not transparent and uncertainties were not well documented) with the result that policy makers and regulators have wound up defending a system of protection that they poorly understood. Reactions of the public, labor unions, special interest groups and the press resulted in the courts being the final judge and interpreter of radiation protection policy.

For the future, it was proposed that we should democratize radiation protection policy by opening the dialogue and forums to the public, unions, policy makers (politicians), press, and courts and require federal agencies to achieve consensus on radiation protection requirements. This would require an advisory committee for all new rulemakings. Shared responsibility would require agreement on resolving issues, involving all parties and would result in final policy which could be implemented in an efficient and effective manner, despite the uncertainties of science. This approach has been used effectively in beryllium rulemaking in the U.S. and in resolving the issue of contamination in the Marshall Islands.

Psychological Factors

Lennart Sjöberg traced the historical evolution of thinking on social issues and pointed out that in the 1970s the so-called psychometric model was published. The cultural theory of risk perception evolved in parallel. However, neither of these models pass the systematic empirical tests that have been done. In the 1980s risk communication (essentially “teaching”) was tried, with disappointing results.

In the 1990s risk communication began to be seen by social scientists as a dead end, and “trust” was suggested as the key factor. It was believed that trust might be established through transparency of policy and

real influence on decision making. But who should be involved, since the silent majority were not interested enough to invest the time needed. Stakeholders seemed to be the answer to representing the public. However, trust does not seem to be a strong factor in risk and related attitudes. People do trust the experts but do not accept their conclusions because the public believes that there are unknown effects and factors that are not understood. Furthermore, stakeholders do not represent the public, but their own particular interests.

While experts talk about risks as probabilities, the public thinks in terms of the severity of consequences, and this is the key difference in the view points of experts and the public. We haven't really understood how to deal with this yet.

Ethical Issues

Deborah Oughten said that ethical values are complex in risk evaluation, particularly when science cannot identify a safe level of radiation. There is a problem with risk and benefit being distributed over different populations at different times. However, recommendations are vague as to what ethical values should be incorporated into radiation protection. From an ethical standpoint, the following questions might be included: Do the benefits outweigh the costs? Is the distribution of risk and benefit equitable? Have affected people been involved in the decision making process? Is there a viable alternative? Does the person have control over (or has the person given consent to) the risk? Has the person been compensated for the risk?

The justification principle is in line with the ethical principle that one should do more good than harm. However, net benefit is not usually adequate to deem a practice ethically justifiable. Although the ALARA principle has been criticized both for putting a price on human life and for causing an excessive use of funds, there are strong ethical grounds for retaining some form of optimization in radiation protection policy. However, authorities should guard against pursuing cost-effectiveness without due consideration of other ethical values.

Dose limits are criticized by some people who feel they are too high and by others who feel they are too low. They usually only relate to humans and not other species. Small harms, while never ethically irrelevant in themselves, may be deemed trivial and not worth the investment of resources for regulation or control.

Session 4: International Organizations and Policy Making

This session focused on the role of international organizations in the policy-making process. Abel Gonzalez discussed IAEA activities in the policy arena. IAEA is promoting an international radiation safety regime to foster international consensus on radiation issues and facilitate the solution of problems faced worldwide in regulation of

radiation.[2] The regime's key elements are legally binding international undertakings by states, globally agreed

international safety standards, and provisions for applications of standards. The scientific policy supporting the regime is formulated by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) for the scientific database on radiation health effects, and the International Commission on Radiological Protection (ICRP) for the radiation protection recommendations. The regime serves as a decision aiding mechanism which should be coupled to societal and other concerns (e.g., stakeholders) in the decision making process.

Roger Clarke discussed ICRP activities. Recommendations on radiation safety are the main role of the ICRP. Over
the past 60 years of its existence, the ICRP has continually evolved as radiation knowledge developed. Initially, the
ICRP focused on prevention of deterministic effects. Now, the ICRP is concerned mainly with recommendations
related to probabilistic/stochastic effects (e.g., cancer); from simple severity thresholds to dose effects relations

[2] Under Article III.A.6 of the IAEA Statute, the Agency is authorized "to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property." Details about IAEA safety standards may be found in: IAEA (1999) *Measures to Strengthen International Co-operation in Nuclear, Radiation and Waste Safety*, IAEA General Conference Document GC(43)/INF/8, Vienna: IAEA; and, Safety Standards (1998) *IAEA Bulletin* 40(2).

and
a precautionary as low as reasonably achievable (ALARA) philosophy and acceptable risks; from the idea that
protecting society also protects the individual to a focus on individual risk and averting individual doses.

Burton Bennett provided an overview of UNSCEAR activities. UNSCEAR, created in 1955 to monitor atmospheric weapons fallout, has served as an international resource and database for radiation levels worldwide. Its periodic reports to the United Nations General Assembly now include scientific summaries and integration of the world literature on fallout, health effects, natural background radiation, adaptive response, and practices involving radiation.

Geoffrey Webb discussed the International Radiation Protection Association (IRPA). IRPA is a global association of radiation safety and protection societies. It sponsors international and regional congresses. It promotes the role of professionals in development of policies and standards, has developed a code of ethics, and emphasizes rationality and stability in supporting the profession of health physics.

Patrick Green discussed activities of Friends of the Earth. This organization strives to enhance the societal role in developing and monitoring radiation policy. It encourages increased activity by industry in managing its radiation legacy. It fosters increased societal, ethical and political values in the decision process and in policy development. Above all, it emphasizes the need for justification of decisions and actions and openness and transparency in the "debate."

Session 5: Regional and National Policies

This session was devoted to discussions concerning development of regional and national radiation policies.
Overviews were provided by John Loy (Australia), Kaare Ulback (European Union/Denmark), Kun-Woo Cho
(Korea), and Stephen Page (United States). The following summary emphasizes the key messages from the session,
rather than providing a précis of each speaker's presentation.

ICRP plays a central role in determining radiation policies among countries represented in the session.Translation of
ICRP recommendations into highly binding directives differs from one country to the next, but in all cases takes a
long time (five years at least in Australia). Because of the effort needed to transform ICRP recommendations into
regulations (and for other reasons), "stability" in ICRP recommendations is desirable.

In the European Union (at the moment 15 member states) the Euratom Treaty of 1957 requires uniform basic safety standards to be set in order to protect workers and the public from health risks of exposure to ionizing radiation. Since 1959 seven revisions of the *Standard Directive* have been negotiated and put into force in Europe. These revisions have been based on the latest recommendation from ICRP and have supported the basic principles of radiation protection (justification, optimization, dose limitation), and licensing procedures (reporting and prior authorization of practices). The present *Standard Directive*, adopted on 13 May 1996 by the Council of the European Union, is based on the 1990 recommendations of the ICRP (ICRP Publication 60) and is to be implemented by the member states before 13 May 2000. Being minimum directives the actual incorporation into national legislation is left to the individual member states. Minor differences in the detailed regulations among member states may be expected.

International cooperation in crafting radiation regulations is happening and is useful, but difficult. For instance, U.S. flexibility is somewhat limited by historical regulatory and legal actions requiring lifetime risks $<10^{-4}$. It seems most attainable in areas of shared interest where there is clear need for harmonized regulations, e.g., standards for commodities (contaminated metals) and environmental restoration of contaminated sites (shared problem).

Public confidence in regulations and policies is important in all countries represented on the panel. It is especially critical in Korea where past mistakes, distrust of military dictatorship and memories of the atomic

bombings create significant fear of radiation and where economic development is dependent on nuclear power. Public confidence is thought to improve if radiation policies and regulations are established in an open atmosphere; there is some evidence of increasing moves toward more public participation. For example, Australia now includes a representative of the public on its chief authoritative radiation review board.

It is highly important to establish national/regional radiation regulations in which the public has confidence. Billions of dollars are being spent on cleanup at U.S. Department of Energy contaminated sites. One must do this right and apply resources to sites appropriately. There is some urgency and decisions are being made now.

Session 6: From Science to Policy and Regulations

This session addressed the reconciliation of science, international recommendations, and governing policy in the formulation of regulations. Overviews were provided by Klaus Becker (Germany), David Michaels (United States), Annie Sugier (France), and Tsutomu Sugahara (Japan).

The session focused on developing needed regulations. The "givens", which had already been discussed in the meeting, were the science, with its inherent uncertainties, the activities of the various international and national bodies, and the policies that the various bodies had developed. Regulations need to reflect these policies.

Richard Osborne opened the session by reflecting on the tour that the Conference attendees took to Thomas Jefferson's home, Monticello, the previous day. He noted that Jefferson would like the goals of our Conference and that it was Jefferson himself that said "Knowledge is happiness." This session should bring together the knowledge that we have; the audience should be happy despite the differing opinions. Getting this last step right is key, though; regulations are where the "rubber meets the road."

Annie Sugier emphasized that the common theme of the session was that "Working together is the key." She pointed out that this needs to be achieved at the national and the international level and, most importantly, at the local level. There are a number of aspects to this: shared responsibility, value judgments, paradoxes, misperceptions, non-science issues, and science not being taken for granted. She stressed the necessity to structure the debates making a clear distinction between the different stages of radiological risk management and acknowledging the existence at each stage of not only scientific and technical aspects but also judgements by experts that need to be explained.

Several speakers pointed out that there is a responsibility for all those who are generating policies and regulations to ensure that all who are involved can state their views and be comfortable that their voices are heard. The corollary of this is that there is a responsibility of those so involved to work towards constructive solutions.

There will be value judgments both in setting the policies and developing the regulations. Much of the confusion and angst that arises in reactions to regulations arises from failure to have made such value judgments explicit.

Paradoxes are also commonly a part of the picture. Klaus Becker gave a vivid example of the paradox that occurs with radon. It is accepted and even promoted as a health benefit in radon spas while governments try to emphasize the importance of controlling it in the home. These paradoxes will continue to arise because of the approach that is necessarily taken in selecting for the purposes of protection a single theory for the relationship between radiation exposure and effects on health. He felt that the LN-T theory was not necessarily the most appropriate one.

David Michaels used the example of radioactively contaminated nickel from DOE in steel that might get into orthodontic braces as well as other commercially-used products. He noted that recycling metals may be the right thing to do but we need to involve the public in helping to deal with their issues and concerns.

Tsutomu Sugahara voiced concern that more attention needs to be paid to the uncertainties in the science that underlie the development of regulations. He noted examples where biological endpoints that show a response to low doses of radiation may. in fact, not be correlated with cancer causation. He cited the "trans-scientific" nature of the science for risk management that is involved here. In these situations, he felt that the standards to be developed needed to reflect the views of a large peer community, including the public. Risk

assessment was essential and Sugahara suggested that the medical and engineering fields could provide help in solving this particularly difficult risk assessment problem.

Questions and comments dealt with how we can compare different kinds of risk so that money is not spent to reduce types of risk that are low. A common theme was that unless the people affected are involved in making the decisions and value judgments, they are unlikely to accept the outcome.

Session 7: Problems and Options

This session focused on the main problems in implementing present radiation policy and whether (and how) such policy should be changed. Roger Clarke contended that the current international system for radiation protection, stemming from the ICRP's 1990 recommendations, has a number of problems. In general, it is overly complex and incoherent. Specific problems include difficulty in classifying certain situations as practice or intervention, no limits in emergency situations, and misuse of collective dose. He proposed a simpler approach based on controllable dose, recognizing that if the dose to the most exposed is controlled then the total risk is acceptable.[3] His approach would involve an individual dose scale, which would take into account background radiation and provide a basis for policy making. Criteria could be presented on doses that are fractions or multiples of background and there would be a level (e.g., less than 0.03 mSv) below which dose would be considered trivial. ALARA would be replaced with ALARP (i.e., as low as reasonably practicable), and the concept of "justification" would be elevated to a higher decision making level. In addition, it would no longer be necessary to differentiate between occupational, public and medical exposures. Finally, this approach could be a basis for developing an environmental radiation protection policy.

Helen Garnett referred to four cases to demonstrate the deficiencies in the application of the current system, both nationally and internationally. She too called for a simpler approach embodying greater harmonization of standards and their application that would be helpful to countries where regulatory practices are still evolving as well as those where they are mature. This simpler system should: (a) embody a practical approach to declassification/exemption of material previously classified as low-level waste where, with further evaluation against newer principles/criteria, classification would no longer apply, and (b) eliminate the often inappropriate automatic application of the collective dose approach. Such a system should be based on "protection of the most exposed individual" in appropriate circumstances. Like Clarke, she also saw a need to move away from the distorted ALARA approach so often used where the interpretation is just as low as achievable, to a more flexible standard taking into account social and economic issues. Garnett stressed that the lack of international consensus on science issues leaves open the possibility that low operational doses can lead to unnecessary public concern. She sees utility in providing to workers and the public explanations of dose in terms of natural background and air line travel. In this connection, she recommended that policy makers and the public be informed that 1mSv is a level below which there is uncertainty about the effects of chronic low dose exposure. Such a level is equivalent to the dose received by airline travellers making 4 round trip flights per year between Sydney and London. Decisions need to take into account social, economic, and political factors, although doses at very low levels (e.g., 0.25 mSv) corresponding to one round trip flight between Sydney and London could be considered trivial.

Maurice Tubiana focussed his presentation on the LN-T approach of the current system. He stressed that there is no evidence of carcinogenic effect at doses below 100 mSv and that LN-T theory is not compatible with data from a number of studies or with the complexity of carcinogenesis. In addition, he noted that the LN-T theory actually has demonstrably detrimental effects, having fueled unnecessary anxiety in the aftermath of the Chernobyl accident, leading the public to resist medical and other useful non-power applications of atomic energy, and necessitating disproportionate expenditures with respect to very low risks. He called for a clear statement that the LN-T theory cannot be used to predict the number of cancer risks below 50 mSv. Like Clarke and Garnett, he expressed misgivings about the ALARA principle, which he said was misleading because it indicates that even the smallest dose is harmful. In this regard, he noted that when all data are considered together (including those corresponding to osteosarcoma induced by radium in the dial painters and hepatoma in patients having received thorotrast), the only simple dose-effect relationship which fits all the data is the quadratic one. With this relationship the effect becomes extremely small when the dose is very low. Tubiana advocated more research to demonstrate whether the relationship between dose and effect is better explained by

[3] Controllable dose may be defined as the dose or the sum of the doses to an individual from a particular source that can reasonably be controlled by whatever means. Details about the controllable dose concept may be found in: Clarke, R. (1999) Control of low-level radiation exposure: time for a change? *Journal of Radiological Protection* 19(2): 107-115.

a quadratic relationship rather than the LN-T theory. He called for a more balanced approach to risks from nuclear and other sources and emphasized that public health measures should be determined on the basis of a rational assessment of their cost and benefits. Tubiana said there was a need to base radiological protection on new concepts, as proposed by Clarke and Gonzalez, related to doses which require intervention, monitoring, or are considered negligible.

Nils Diaz pointed out that the scientific debate relative to radiation protection must be of high quality to be useful to policy makers or it will likely delay policy. In any case, the nuclear debate, including radiation protection issues, cannot be carried out only at the scientific level, but must incorporate social, political and economic issues. Moreover, there is a pressing need to educate the media on nuclear/radiological issues, including the cost to society for radiation remediation, and to have more stakeholder involvement in a transparent decision-making process. Diaz saw merit in moving to a system based more on individual than collective dose/risk and said he would support consideration of such a system once it might become finalized. In any case, it was necessary to eliminate the application of collective dose to very low doses in large populations and/or doses delivered over long time periods, although its use as a performance indicator was justified. He also stressed that no radiation dose was below regulatory concern, although certain levels should be below regulatory action. He noted that the validity of the LN-T or threshold theories are not known and therefore it was necessary to focus on the relevant application to today's issues. What is needed is a ten-year hiatus during which relevant research would continue, interim policy would exist, and decision-making could proceed taking into account dose levels at which there is confidence that health effects from radiation are indistinguishable from existing everyday health effects. Finally, he noted the NRC is going through a period of change which provides an opportunity to consider new approaches.

CONFERENCE CONCLUSIONS AND RECOMMENDATIONS

The conference conclusions and recommendations were based on discussions in plenum and responses to breakout group questions. A number of conference conclusions and recommendations were suggested. Considering that many recommendations were not fully considered because of the lack of time, the participants agreed that another conference should be organized to further develop these and other recommendations. The following list reflects these conclusions and recommendations that received the broadest support.

Conclusions

- Ionizing radiation is a well-known human carcinogen. During the past 50 years numerous epidemiological studies of adult human populations exposed to radiation from medical, occupational, or military purposes have been conducted. The lowest dose at which a statistically significant radiation risk has been shown is ~ 100 mSv. This does not imply the existence of a threshold.
- The effects of low-level radiation below 1 mSv per year above background radiation cannot currently be distinguished from those of everyday natural health hazards.
- The concept of collective dose is often misapplied, e.g., to estimate health impacts of very low average radiation doses in large populations and/or doses delivered over long time periods. Collective dose can be a useful comparative tool, for instance, in the evaluation of protection options.
- It is essential to continue to foster international cooperation in radiation safety. In particular, international harmonization of radiation safety policies for radiation sources delivering low radiation doses should be developed.
- Consistent and coherent radiation policy on a national level is necessary for the effective implementation of radiation safety.
- Economic, environmental, ethical, psychological, and scientific factors are all essential in the policy and regulatory decision-making process to assure public health and well-being. The way in which these factors are incorporated in nation-specific decision-making processes may vary.
- Concern over low doses should not deter the public from obtaining benefits of medical procedures.

Recommendations

Policy and Regulatory Process

- Policy discussions on the regulation of radiation sources delivering low-level radiation should include

references to natural background radiation.

- The conference supports the evolving global framework of the International Atomic Energy Agency (IAEA) for the safe use of radiation.
- The conference supports further development and evaluation of the ideas associated with the proposal on controllable dose.
- No radiation dose is below regulatory concern but certain levels should be below regulatory action, and appropriate dose levels should be established.

Science

- Fundamental questions about the shape of the dose-response curve and mechanisms of effects of radiation at low doses are unlikely to be answered in the near future. Scientific research, including molecular and cellular radiobiology studies are critical in order to better understand mechanisms of radiogenic effects, and providing important information about the likely shape of the dose-response curve at low doses of radiation, and should be coordinated and continued.
- Multinational support and analysis of human data derived from studies such as the Radiation Effects Research Foundation (RERF) Life Span Study , the Russian Mayak and Techa River studies, nuclear workers studies, and studies of populations living in high natural background areas to assist in reducing scientific uncertainties in risk and in elucidating mechanisms of radiation health effects are strongly encouraged. These data offer a unique opportunity to further quantify effects at low doses in human populations.

Constituent Concerns

- Groups involved in the development of policy and regulations, or making recommendations for such policies and regulations, should operate in an open and transparent manner, and engage in dialogue with stakeholders.
- There is a pressing need for more effective communication by scientists with the public, politicians, policy makers, regulators, and other interested persons. The science should be clearly articulated, emphasizing what we do and do not know, explaining the limitations in the information, and what we are doing about it.