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Public Health Regulation and Control of Population Exposures to Ionizing Radiation

J.I. Fabrikant

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Biology & Medicine Division

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PUBLIC HEALTH REGULATION AND CONTROL OF POPULATION

EXPOSURES TO IONIZING RADIATION [1,2]

Jacob I. Fabrikant, M.D., Ph.D.
Professor of Radiology
University of California,
Berkeley and San Francisco, California

Donner Laboratory and Donner Pavilion
Lawrence Berkeley Laboratory
University of California
Berkeley, California 94720

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Introduction

My assignment today is to provide you with some understanding of public health regulation and control of population exposures to ionizing radiation--in the environment and in the workplace. I think the best thing for me to do is to discuss four general problems. First, what are the sources of ionizing radiation of concern that impact public and worker health and safety? Second, what is the history of research on the health hazards in populations exposed to low-level radiation as it affects public health regulation and control and standards-setting? Third, how is this managed from the point of view of government officials responsible for protecting the health of the general and worker populations? And fourth, how does new knowledge emerging from the research on the health hazards of low-level exposure to ionizing radiations become translated into practical guidance for use by politically responsible officials?

My knowledge of the situation in the United States is perhaps the most appropriate for our purposes today. I shall not attempt comparisons, nor even judgments, on how public health, public policy and decision-making come together in the area of the risks of low-level radiation, how we understand them and how we protect against them---at least in the United States today. The matter is complex, and I shall try to explain why this is so.

I shall not deal today with specific numerical risk values, nor how governmental guidance and standards-setting are designed to protect the public health and safety. What appears to be important to today's discussion are the basic principles underlying radiation protection philosophy---that: (1) Any radiation exposure may involve some degree of risk, i.e., the probability that a given individual will incur a deleterious health effect as a result of a dose of radiation. (2) This will involve some degree of detriment, i.e, the expected harm incurred from the radiation dose. (3) The principal objectives of radiation protection are to limit the radiation dose in appropriate procedures to levels where these probabilities are acceptable, to avoid any unnecessary exposures, and to ensure that the radiation doses are justifiable in terms of benefits that would not otherwise have been received.

The Sources of Ionizing Radiation and Radiation Risk Abatement

The general public receives the major portion of its radiation exposure from natural background sources, both cosmic and terrestrial including radon daughters, and from a series of medical sources including radionuclides, x-ray generators, and particle

accelerators used for diagnosis and treatment of disease. Currently, the annual effective dose equivalent received by the U.S. population from both of these sources is approximately 0.36 rem (3.6 mSv).[1] Subgroups of the population receive additional radiation exposure in the workplace. These include radiologists, medical technologists, the employees of nuclear industry, and miners of uranium and other materials who work in formations rich in radioactive materials. The average annual dose equivalent resulting from the occupational exposure of radiation workers is approximately 0.9 rem (0.009 mSv). The dose-equivalent from natural, medical, and other sources of radiation received by the general public and by radiation workers may be expected to contribute 3% or less to the cancer morbidity and mortality statistics for the United States. Because this percentage is small, some might be tempted to argue that efforts to reduce radiation dose levels both in the public at large and in radiation workers are unnecessary. However, many individuals may be exposed to radiation levels several times higher than these averages. Moreover, even those average levels are sufficiently high to require vigilance as the applications of radiation technology in medicine and industry continue to proliferate.

Exposures from Cosmic and Terrestrial Sources

The dose equivalent from natural background radiation depends on many variables associated with the radiation's origin. For example, radiation from cosmic sources is closely related to altitude. The annual cosmic dose equivalent at mile-high Denver (55 mrem or 0.5 mSv) is approximately double that received annually at such coastal cities as Boston, New York, and Philadelphia (27 mrem or 0.3 mSv). The terrestrial sources of background radiation are radionuclides present in the earth or those that have transferred from the earth to the atmosphere or hydrosphere. Almost all are primordial in origin, and have been here since the earth was formed. Many of them are isotopes of heavy elements belonging to three radioactive series headed by uranium-238, uranium-235, and thorium-232. In ground surveys in the United States, dose rates in air from natural terrestrial radiation have been found to range from 4 to 180 mrem/y (0.04 to 1.8 mSv/y).[2]

A terrestrial radionuclide of increasing importance to public health is radon-222, a noble gas and a decay product of radium-226 in the uranium-238 series.[2] This gas emanates from the soil and from building materials of terrestrial origin, e.g., stone, bricks, and concrete. Radon and its daughter products seep into homes and office buildings and, when ventilation is restricted, may accumulate in concentrations substantially higher than those prevailing outdoors. In response to the recent need to conserve energy in the heating

of homes and office buildings, construction methods that sharply restrict ventilation have been introduced. The control of radon progeny levels is becoming increasingly important. Outdoor concentrations of radon-222 and its progeny range from about 0.2 pCi/L (7.4 Bq/m^3) to more than 10 pCi/L (370 Bq/m^3) at ground level. Indoor levels are only moderately higher, average about 1.5 pCi/L (55 Bq/m^3) when ventilation is not greatly restricted. In contrast, radon concentrations of 10 pCi/L (370 Bq/m^3) to 100 pCi/L (3,700 Bq/m^3) or more have been measured in some older homes in certain geographic locations, and in recently constructed homes designed to limit ventilation as far as possible. Overall, the average annual dose equivalent to the bronchi from radon daughter products is about 2.4 rem (24 mSv)[1].

The tissues at risk from exposure to radon include the surfaces of the bronchi, segmental bronchioles, and alveolar membranes. These tissues are exposed primarily to radon daughters, e.g., polonium-218, which attach themselves to dust particles, and, when inhaled, deposit themselves within the respiratory system at locations influenced by particle size. Radiation exposure is attributed primarily to alpha particles. The epithelium of alveoli receives an estimated dose equivalent of approximately 0.5 rem/y (5 mSv/y) when radon concentrations in air are 10 pCi/l (370 Bq/m^3). The dose equivalent of the segmental bronchioles may be approximately 5 times higher. Continuing research and surveillance is monitoring radon concentrations in homes and other structures. Moreover, methods of dose reduction are being introduced to assure the conservation of heat while simultaneously preventing substantial buildups of radon progeny concentrations in the indoor ambient air. Sealing techniques, which prevent radon seepage through basement floors and walls, is an important component of any program to reduce risk from this source.

Exposures from Medical Sources

The medical uses of ionizing radiation have increased rapidly over the years, especially in diagnostic procedures. Currently, one-half of the United States population is examined radiographically each year. A substantial portion is also examined with procedures involving radionuclides. The average annual dose equivalent of the general population from medical sources is approximately 0.063 rem (0.63 mSv), roughly one-fifth that received from natural background sources.[1]

In the United States, the Food and Drug Administration, Department of Health and Human Services, is the federal agency primarily reponsible for national policy with respect

to medical sources of ionizing radiation.[3,4,5] It has a major interest in dose reduction and has supported research, which has been transferred to practical guidance, aimed at improving medical radiation technology. The diagnostic information yielded by a radiological procedure is closely linked to radiation dose levels. Therefore, great care is exercised to assure that the diagnostic information yielded by the procedure is not compromised when doses are reduced. In recent years, radiological imaging scientists have been quite successful in developing technologies for reducing radiation doses without loss of diagnostic information. Similarly, research in radiation oncology is actively directed at risk abatement, i.e., reducing the dose to normal tissues as much as possible while providing a tumoricidal dose to the cancer. As increasing numbers of cancer patients, especially in the younger age groups, are cured of their disease through radiation treatment, as in the case of Hodgkin's disease, methods must be further improved to reduce the probability of subsequent development of radiation-induced tumors.

As the uses of ionizing radiation in medicine continue to increase, a program of research on medical applications and dose reduction has become an important component of the national research agenda on the biological effects of ionizing radiation. Unless this is fully recognized, diseases resulting from exposure to ionizing radiations from medical applications, particularly from newly-introduced technology such as the computerized tomographic scanners, could rise to unacceptable levels, substantially higher than those now prevailing.

Occupational Exposure

In most instances, radiation exposure in the workplace has been reasonably well controlled, particularly in medical technology and radiology, and in nuclear power plants and radioactive waste disposal programs. A notable exception is the uranium mining industry, where it has been especially difficult to maintain ambient radiation levels within acceptable limits to protect worker health and safety. Because of high exposure to radon and its daughters in the past, in mining environments exceeding 10 pCi/L (370 Bq/m^3) the incidence of lung cancer in uranium miners is elevated.[2] Amelioration of the problem through improved methods of radiation control has been difficult because in the United States, primarily because public health authority over the mining industry has been divided among a number of federal regulatory agencies.

Among an estimated 16,000 people in the United States who have been employed in operations that could involve exposure to plutonium, approximately 5,000 have some evidence of internal plutonium deposition.[2] Until recently, the United States Department of Energy supported research to increase the removal of plutonium and transplutonium elements from the body by means such as chelation therapy.[6]

The Scientific Basis of Radiation Protection Philosophy

Radiation protection had its foundations within the medical profession in the early part of the twentieth century. Both acute health effects and serious late effects were directly observed when humans were exposed to sufficiently large doses of radiation from x rays and natural radionuclides. Acute effects, such as erythema, were seen only above some level of dose that became known as a *threshold dose*. Serious late effects such as malignancy were more difficult to evaluate because they occurred with such low frequency that they were observed only after substantial exposure of large groups. Consequently it has never been possible to demonstrate that a threshold dose exists for these late effects such as cancer or genetic ill-health. Over a substantial range of doses, from about 20 rads to a few hundred rads (0.2 Gy to a few Gy), the level of carcinogenic risk appears to be related to the level of exposure in a manner such that the risk increases with increase in exposure.[1] This consideration, in addition to the further adoption of the conservative hypothesis of a linear relationship between biological risks and the amount of dose down to the lowest dose levels, has determined the basic approach to radiation protection during the past 30 years.

Two assumptions are necessary for risk estimation for purposes of radiological protection: (1) the possibility that there may be no threshold for induction of deleterious late health effects following exposure to radiation and, (2) that the relationship between the probability of such deleterious effects and dose may be a linear one. As a result of these assumptions, no level of exposure to radiation can be considered to be without risk. Furthermore, if society wishes to carry on activities resulting in exposures to radiation it is necessary to aim at environmental and workplace conditions such that the real and potential risks to health can be made less important than the benefits to individuals and to society from activities which result in the exposure. And finally, any further reductions in the risks become less important than the effort that would be required to accomplish such reductions. For occupational exposure, the hazards should not exceed those that are accepted in most other industrial or scientific occupations with a high standard of safety. The risks to members of

the public from man-made sources of radiation should be less than or equal to other risks regularly accepted in everyday life, and should be justifiable in terms of benefits that would not otherwise be received.[7,8]

Federal Government Involvement in Ionizing Radiation and the Protection of the Public Health

Scientific research, regulation and protection in the field of ionizing radiation impacting public health and safety were pursued largely in the private sector following the discovery of X-rays by Wilhelm Conrad Roentgen in 1895 and to the advent of World War II. Government involvement in radiation research was indirect, being limited essentially to the support of educational, research, and health care institutions that might have had an interest in health effects research and control of ionizing radiation. Following the establishment of the Manhattan Project and the development of the atomic bomb by the United States, the federal government became increasing involved in the development, application, regulation, and control of ionizing radiation to protect the general public and worker populations.[9] A number of institutional arrangements evolved among federal agencies, private industry, and educational and research institutions in order to conduct applied radiation research in support of government missions. Direct participation of the government was maintained at different levels, depending upon the specific arrangements.

Prior to the federal government's initial investment in the development of the atomic bomb, major interest in ionizing radiation was centered in the medical, academic, and industrial sectors. Since there was early evidence of radiation health hazards in exposed human worker populations, such as acute skin burns and, later, skin tumors, scientific interest in radiological protection was stimulated. This led to the establishment, in 1928, of the International Commission on Radiological Protection (ICRP)[7,8], followed the same year by the creation of an American counterpart organization, the Advisory Committee on X-Ray and Radium Protection, which became chartered by the Congress of the United States as the National Council on Radiation Protection and Measurements (NCRP)[10] in 1964. Both organizations are composed of groups of scientists in the private and public sectors who study and report on various aspects of the public health and safety as regards protection against ionizing radiation. The International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements have played major roles in the analysis of data and dissemination of information in the field of radiation

protection and measurements and remain singularly active and productive nongovernmental institutions today.

United States Atomic Energy Commission

In December 1938, the discovery of nuclear fission launched the new field of atomic energy. By 1939, Szilard, Fermi, and their colleagues had raised the possibility of creating a controlled explosive device using atomic energy. By 1941, the National Academy of Sciences' Uranium Committee was actively examining the subject. Between 1943 and 1947, the United States government invested large sums of money in the development of nuclear weapons; the larger portion of the cost of this research and development program was borne by the budget of the War Department for the Manhattan Engineering District.[9] The Military Appropriation Act for 1947 had the first public reference to atomic energy in this series of appropriations.[11] Through the wartime research and development efforts, not only was a large base of physical and biomedical information created that impacted public health and control and regulation of ionizing radiations, but also a complex set of relationships was established among the federal government agencies, the National Academy of Sciences, the academic scientific community, and the industrial sector.

The first military use of an atomic weapon occurred in 1945. In recognition of the potential of the technology and with the military research experience as a guideline, the United States Congress enacted the Atomic Energy Act of 1946[11]. The Act created the United States Atomic Energy Commission (AEC) and empowered it with the responsibility of conducting research and development programs directed at the use of fissionable and radioactive materials for medical, biological, or military purposes and the protection of human health during research and production of fissionable materials. A further refinement of these concepts was embodied in the Atomic Energy Act of 1954[12], which required the United States Atomic Energy Commission to conduct research and development for both military and peaceful uses of atomic energy, including: military applications; processes, materials, and devices that can be used to produce nuclear energy to generate electricity; safety during research and production of fissionable materials; and medical, biological, agricultural, and health purposes. In conjunction with these obligations, the Act strengthened the role of the United States Atomic Energy Commission in regulatory responsibilities and controlling the use of fissionable materials in order to protect the public health and safety against the risks of ionizing radiations. It was through this series of legislative developments that both major governmental roles in the atomic field were

defined: research for production and research for protection, regulation and control. They were combined in the charge to a single agency, the Atomic Energy Commission.

Although the United States Armed Forces occupying Japan, using both Japanese and American scientists, gathered initial data to determine acute medical effects in the radiation-exposed populations of Hiroshima and Nagasaki, it soon became evident that a long-term integrated study would be necessary. In 1947, the Atomic Bomb Casualty Commission (ABCC) was formed within the National Academy of Sciences (NAS)[13]. First supported by the United States military occupational forces, this Commission beginning in 1949 to the present received funds from the United States Atomic Energy Commission, now the United States Department of Energy (DOE). In 1975, the program was transformed from a project directed and funded entirely by the United States to a combined study under joint Japanese and American direction and funding. It was renamed the Radiation Effects Research Foundation (RERF)[14], and the United States effort continued within the National Academy of Sciences.

Scientific Committees and Councils

Independent of governmental initiatives, and in response to nuclear weapons testing and public concern about the potential effects of ionizing radiation on human populations, the National Academy of Sciences, formed the Committee on Biological Effects of Atomic Radiation (BEAR)[15] to study this subject. The BEAR Committee issued a series of reports between 1956 and 1963.[15] The General Assembly of the United Nations in 1955 established the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)[16]; its tasks were associated with monitoring and assembling reports of radiation exposure throughout the world, radiation levels and radiation effects on man and his environment.

The Executive Branch of the United States Government

In 1959, the United States Executive Branch of government created the Federal Radiation Council (FRC) within the Executive Office of the President to provide advice and guidance for policy on radiation exposure of humans in the formulation of radiation standards for protection of the public health and safety[17]. The Federal Radiation Council consisted of the Secretaries of the Department of Health, Education, and Welfare; Defense; Commerce; Labor; and the Chairman of the Atomic Energy Commission and others appointed by the

President of the United States. It comprised consulting scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the NCRP, and qualified experts in biology, medicine, and health physics.

In 1970, the Federal Radiation Council asked the National Academy of Sciences to undertake a complete review and evaluation of existing scientific knowledge concerning radiation exposure of human populations. That study was the 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiation (the BEIR I Report)[18], and examined all the biological and health research and epidemiological evidence pertaining to the effects of ionizing radiation on human populations. The Committee provided conservative quantitative estimates of the risks of untoward effects, cancer induction and genetic disorders, of exposure to low levels of radiation exposure. Subsequently, these risk estimates were used by United States regulatory agencies in setting radiation standards for limiting occupational and public exposure. Since that time until 1990, there have been five BEIR reports issued by the National Academy of Sciences.[1,2,18,19,20]

United States Federal Agencies

The United States Environmental Protection Agency (EPA) was established by the President in 1970;[21,22,23] the functions assigned to it were those of the Federal Radiation Council and the environmental radiation standards-setting functions of the Atomic Energy Commission. For the first time, federal responsiblilities for radiation protection were separated from those for development of applications. The establishment of radiation standards for the protection of the general environment from radioactive materials was now an Environmental Protection Agency function, and responsibility, subsequently including the regulation of the discharge of radioactive materials into navigable waters, to protect drinking water supplies, to regulate the recovery and disposal of all radioactive wastes, and to regulate airborne emissions of radioactive materials.

As further changes in administration of radiation programs evolved, the controls were applied directly by the United States Department of Defense (DOD) and the Atomic Energy Commission in their own operations, primarily dealing with nuclear weapons production and testing, and the disposal of radioactive wastes resulting from nuclear weapons.

A congressional act of 1974 dissolved the United States Atomic Energy Commission entirely and created two new agencies to assume the Atomic Energy Commission's remaining functions: the Nuclear Regulatory Commission (NRC), which assumed the Atomic Energy Commission licensing and remaining regulatory functions, and the Energy Research and Development Administration (ERDA), which was charged with conducting research and development for both military and peaceful uses of atomic energy.[24] When setting radiation standards became the responsibility of the Environmental Protection Agency and the licensing and regulatory activities were assigned to the Nuclear Regulatory Commission, the control functions pertaining to radiation became further separated from the activities related to research, development, and application of atomic energy.[6,25,26,27]

The Department of Energy Act of 1977[6] created the Department of Energy (DOE) and transferred to it the responsibilities of Energy Research and Development Administration. The Department of Energy was given the responsibility for developing and producing nuclear weapons systems for the Department of Defense in facilities owned by the Department of Energy, but operated by private companies and universities. Furthermore, it was charged with developing peaceful applications of nuclear energy and technology, especially nuclear power sources, in cooperation with private companies, and radiosisotopes for medical and industrial applications.

Other Federal Agencies

In addition to these chains of responsibility, several other federal organizational functions were and are active in parallel with the Atomic Energy Commission-Environmental Research and Development Agency-Department of Energy and the Federal Radiation Council-Environmental Protection Agency activities.[18,21,22,23]

The Naval Nuclear Propulsion Program, jointly operated by the Department of Defense and Department of Energy, develops and supports the reactors for a fleet of nuclear-powered submarines and surface ships. Health care facilities dealing with ionizing radiation are administered by the Department of Defense, the Veterans Administration (VA), and the Department of Health and Human Services (DHHS); the Department of Health and Human Services sponsors research involving the use of radiation technology in both health care and basic radiation biology. The Food and Drug Administration (FDA) has the responsibility to provide guidance concerning the use of food and animal feeds containing

radionuclides;[4] it also regulates radiopharmaceuticals and radiation-related medical devices, and sets performance standards for diagnostic X-ray machines and other electronic products that emit radiation. The Nuclear Regulatory Commission[29] oversees licensing of radioisotopes for applications for medical programs. Control of consumer products that are a source of ionizing radiation is shared by the Food and Drug Administration, the Nuclear Regulatory Commission, and the Consumer Product Safety Commission (CPSC), depending on the specific product. The National Aeronautics and Space Administration (NASA) is responsible for the development of nuclear aerospace applications. The transport of radioactive materials or goods is coordinated by the Materials Transportation Bureau, using authorities of the National Regulatory Commission, the Department of Transportation[28] (DOT), and the United States Postal Service. As a separate function, a number of federal agencies are concerned with monitoring and regulating occupational exposures of specific groups to radiation: the Nuclear Regulatory Commission, workers of licensees;[26] the Department of Labors' Mine, Safety, and Health Administration (MSHA), miners exposed to radioactive materials; and the Occupational Safety and Health Adminisration (OSHA), standards for workers other than those covered by the Nuclear Regulatory Commission and the Mine Safety and Health Administrtion. The Occupational Safety and Health Administration may delegate authority to states that meet Occupational Safety and Health Administration criteria. The National Institute for Occupational Safety and Health (NIOSH) conducts research in support of the Occupational Safety and Health Administration regulatory activities.

The United States Department of Health and Human Services also conducts epidemiological studies under the aegis of the National Cancer Institute, Food and Drug Administration, National Institute of Occupational Safety and Health, and Centers for Disease Control; data collection and analysis is conducted by the National Center for Health Statistics. The National Bureau of Standards has a responsibilty for establishing and maintaining reference bases for measurements, data, and materials and for providing infrastructure services for the physical and engineering sciences in matters dealing with ionizing radiation. The Department of Defense deals with radiation research relevant to its primary military mission; hence, most of its research is directed toward the effects of high levels of radiation exposure and those effects principally occurring in materials and in biological systems. The Department of Agriculture uses ionizing radiation as a research tool for the development of new plant strains, especially food grains, and the production of sterile male insects used in pest control systems.

Current Federal Government Management of Radiation Research, Regulation and Control

Despite the appearance of an orderly distribution of separate functions---developmental, regulatory, protection standards, and basic research---overlapping interests have resulted in a less clear-cut discrimination of activites among the federal agencies. The large number of federal executive agency interests in radiation research, regulation, protection and control was reflected in the membership of the Interagency Radiation Research Council (IRRC), which was created in 1980. The IRRC was composed of representatives from all fourteen federal agencies having significant research, operational, and protective functions in the area of radiation. Also established in 1980 by Executive Order was the Radiation Policy Council (RPC), which was charged with formulating and implementing federal policy relating to radiation protection. The current descendent, the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) was assigned responsibilities of the former Interagency Radiation Research Committee and the former Radiation Policy Council. Its overall charge is to coordinate radiation matters between federal agencies, evaluate radiation research, and provide advice on the formulation of radiation policy, its protection standards, and its regulation. There are eighteen Committee on Interagency Radiation Research and Policy Coordination member federal agencies, with fourteen agencies on the scientific panel---USDA, DOE, DOD, DOC, DHHS, DHUD, DOI, DOJ, DOL, DOT, EPA, FEMA, NASA, NRC, VA, OMB, DOS, NSC.

The United States Department of Labor radiological programs are designed either to limit exposure of workers to ionizing radiation or to compensate those workers who may have become ill or died as a result of exposures. Research with regard to the former area is primarily performed by the National Institute for Occupational Safety and Health, though it is possible that some kinds of research may need to be performed by the Department of Labor in the future in support of any new radiation standard proposed. For example, the Occupational Safety and Health Administration or the Mine, Safety, and Health Administration might need to perform an economic impact analysis which would deal with questions such as the numbers of workers exposed and the technological feasibility of compliance.

The Legislative Branch of the United States Congressional Committees

In parallel with the multiplicity of interests in the Executive Branch of government, many necessarily overlapping both the fields of supported research and the research information required for public health and safety, regulation and control, similar legislative interests are represented among the committees of the Congress of the United States. In the United States Senate, the Labor and Human Resources Committee and Judiciary Committee oversee matters of radiation exposures, United States liability resulting from Nevada test site activities, and exposure to medical radiation. The Governmental Affairs Committee is concerned with coordination of federal agencies for radiation protection and research. The Environment and Public Works Committee oversees nuclear power plant safety, while the Energy and Natural Resource Committee is concerned with nuclear waste policy.

In the United States House of Representatives, the Interstate and Foreign Commerce Committee deals with radiation exposure and nuclear power plant safety, while the Interior and Insular Affairs Committee overseees nuclear power plant safety, the Nuclear Regulatory Commission and risk analysis, nuclear safety research, and radium pollution in Colorado. The Science and Technology Committee is responsible for the Nuclear Regulatory Commission and oversees safety research, nuclear reactor safety in the Department of Energy, and nuclear waste research. The Judiciary Committee is concerned with the medical expenses involved in the Hiroshima and Nagasaki atomic bomb explosions. The Armed Forces Committee is responsible for nuclear energy emergencies, while the Government Operations Committee is concerned with environmental radiation programs under Environmental Protection Agency responsibility.

Organization of the Federal Effort

The recent history of federal involvement in ionizing radiation research on public health regulation and control characterized by an increasing dispersal of authority and responsibility. As late as the mid-1950's, the United States Atomic Energy Commission was clearly the dominant agency in the field, holding sole responsibility for nearly every task relating to the formulation of regulatory policy and control. Where once there was an extraordinary degree of centralization in authority, there is now an extreme degree of jurisdictional fragmentation. This dispersal of authority is the result of a number of causes. The dominance of the United States Atomic Energy Commission in nuclear affairs was successfully challenged by those who believed that the promotion and regulation and application of protection standards of technological activities should be vested in separate agencies. The Joint Committee on Atomic Energy[6], which had centralized congressional

oversight of radiation matters, was disbanded in 1977, giving other congressional committees the opportunity to initiate and monitor legislation affecting agencies concerned with radiation. Continued demonstration of the efficacy of radiation in medical diagnosis and therapy [26,27,29] and its importance in basic biological investigations led to a diffusion of radiation-related research among the various federal health research agencies.

A growing concern with environmental and occupational hazards and risks to the consumer brought about the establishment of new federal agencies, some of which were assigned jurisdiction for monitoring and regulating radiation sources. As the number of agencies grew, so did a belief that there was a need to coordinate agency policies in this field. It was feared that agencies would promulgate inconsistent radiation control standards, issue contradictory statements on radiation health effects, and sponsor needlessly duplicating studies, unless their policies were harmonized. The establishment of the Federal Radiation Council in 1959 was the first attempt to coordinate the policies of these federal agencies. In a second attempt, the functions and staff of the Federal Radiation Council were transferred to the Environmental Protection Agency upon its establishment in 1970.[21,22,23] Neither of these efforts at coordination is judged by participants to have been totally successful. The Federal Radiation Council's effectiveness was limited by a policy of obtaining unanimous consent among its members before initiating any action. The Environmental Protection Agency stands as one interested agency among many and is burdened with extremely large and distracting additional program responsibilities.

Interagency Task Forces

During this decade, attempt at coordination stems from the establishment of the Radiation Policy Council to coordinate regulatory activities and the Interagency Radiation Research Council to coordinate research programs; both these agencies are now fused into the Committee on Interagency Radiation Research and Policy Coordination, with combined programs and responsibilities. Originally, it was proposed that both committees be located within the Executive Office of the President in order to elevate their importance within the government and that a minority of their members be representatives of the public in order to enhance the legitimacy of their pronouncements. However, the Executive Order creating them, nor their successor, the Committee on Interagency Radiation Research and Policy Coordination, did not give them either Executive Office status or public membership. It was believed that the Executive Office should not be burdened with additional operational

responsibility and that appointment of a minority of public members to the committees would be an inappropriate way to involve the public in the affairs of the agencies.

The eighteen member federal agencies represented this interagency committee contrasts sharply with the initial membership of the Federal Radiation Council which was limited to only seven agencies. If further reorganization were to produce a recentralization of authority in ionizing radiation research, regulation, and control, the federal governent's credibility in this area is likely to be subjected to even futher questioning. Public acceptance of the results of scientific research is enhanced when the same results are generated by different groups of investigators that use different approaches and have different sources of support. The existence of the current number of agencies supporting radiation hazard research---some with the mission to promote technologies, some with the mission support regulation and control---may appear disorderly, but it does have the effect of increasing the breadth of reliable information pertaining to the health effects of ionizing radiation and providing the opportunity for the development of confirmatory evidence in the field for application to public health regulation and control.

Sponsored Research

Technology-development agencies such as the Department of Energy and the Department of Defense are encouraged to sponsor research on the health risks of exposure to ionizing radiation.[30] Technology development no less than technology regulation should be informed by results of such research. Currently, the United States Department of Energy sponsors slightly less than 50% of the federal research on the biological and health effects of ionizing radiation. A significant portion of the work in the United States is likely to remain in the national laboratories because of the uniqueness of other facilities and capabilities. These agencies pursuing their individual responsibilities cannot ignore or neglect the national need for basic research and scientific training to advance knowledge concerning radiation and health. The pervasiveness and variety of interests in radiation and the need for its regulation makes it unlikely that one or two federal agencies, focused on the health aspects of radiation, could adequately serve all needs. Rather, it would seem that such support and control is best made a government-wide concern. If medical aspects of radiation require special attention, regulation and control, they might be addressed in a program established within the Department of Health and Human Services to consider the research and training needs of health care technologies, guidance, standards and protection.

It does not appear that this matter should receive a disproportionate share of attention by the federal government. Consideration of these health effects apart from other man-made and natural hazards exaggerates their relative dangers and distorts research and regulatory priorities. We recognize that in the United States the public harbors a great fear of the health effects of ionizing radiation, especially its potential for causing cancer and for producing genetic damage. This concern is heightened by the intense and continuing debate over national energy policy, a debate in which some participants have been tempted to resort to the use of unsubstantiated claims about health and safety risks of contending technologies in order to gain advantage for the option they favor. But the government's pandering to these fears hinders the public's ability to appreciate and balance the true risks it faces.

The proposals to add public membership to the coordinating bodies stem partly from a belief that scientists alone should not resolve the issues of safety, regulation, compensation, and policy direction and control that beset the studies of the health effects of ionizing radiation. Certainly, regulatory decisions and public opinion about what is safe or compensable, and the determination of public policies, are political judgments only partially informed by the current state of scientific knowledge, despite the fact that relatively more is known about the effects of ionizing radiation than most other environmental hazards.

What Can We Conclude?

Here, there are three areas of concern: (1) management, regulation and control; (2) public information, and (3) the use of research results to protect the public and worker health and safety.

1. Management of Federal Regulatory Control and Research Programs

There are research goals and standards for protection and guidance---the determination of the health effects of exposures to low level radiation may be among them---that exceed the currently realized and envisioned capabilities of science. Apparently, the public has little appreciation of these limitations. On the contrary, the public places great pressure on political leaders to assure the absolute safety of radiation technologies, in medicine, in energy, and in the workplace reacting emotionally to every reiteration of their potential hazards. In turn, our political leaders pressure our federal agencies to produce immediate and definitive statements of the radiation risks involved, the levels of safety or hazards,

the intent of protective action, and regulatory guidance. Too often the response results in the initiation of studies that are unlikely to yield meaningful results to have practical applications. In the aftermath of the Three Mile Island Nuclear Power Plant accident, for example, there were the inevitable calls for epidemiological studies of the affected populations. These studies were initiated despite the fact that the levels of exposure were such that the demonstration of biological or health effects relating to the exposure was virtually impossible. In a field as socially sensitive as research, control and regulation of ionizing radiation, there is a need for our governmental agencies to seek not only the substance but also the appearance of total objectivity. To be sure, controversy is inevitable in the field of ionizing radiation as in some other fields, given both the limitations of the current state of knowledge and the political consequences of research results and their relevance to public and worker health and safety.

In 1990, the federal government in the United States expects to spend many hundreds of millions of dollars on research on the health effects of ionizing radiation. Most of this work will be sponsored by the United States Department of Energy and the National Institutes of Health, but thirteen other agencies will contribute as well. The prime emphasis is placed on animal models and epidemiologic studies. Many of these studies will fail in attempting to improve our knowledge of low-dose effects, primarily those required to understand the risks of exposure in human populations to low-level radiation. It would appear that more emphasis should be placed on basic science investigations, especially those in cell and molecular biology and biophysics. Such work holds the greatest promise for deepening our understanding of the effects of exposure to low levels of ionizing radiation. In the field of epidemiology, it would appear that effort should be focused on the improvement of investigative techniques, e.g., the use of markers, rather than the initiation of additional large-scale population studies. It also would appear that more attention should be placed on exploring the extrapolation of data from studies of nonhuman systems, i.e., laboratory animal data, to humans. Until there is significant progress in the advancement of investigative techniques for measurement, it is doubtful that there will be important advances in understanding the health effects of exposures to low levels of ionizing radiation, and thus, the attendant risks to society.

2. Public Information

A responsibility of the government in sponsoring research and imposing regulation in association with establishing appropriate standards on the health effects of ionizing

radiation is to inform the public of the risks and benefits of radiation exposure. Surprisingly little is known, however, about the public's attitudes toward radiation and the role that government information programs play in the formation of those attitudes. This is true even if the inquiry is broadened to include public attitudes toward nuclear power generation of electricity, a highly visible and controversial application of radiation technology. In the United States the public is sharply divided on the issue of nuclear power development, its conflicting opinions are held intensely, and the opinions of the antinuclear advocates reflect a variety of fears concerning the health effects of radiation. It is not known with any degree of certainty how these opinions developed or the degree to which they can be modified by additional knowledge. Opinion surveys in the United States and in Europe have failed to probe the dynamics of these public attitudes in any depth.

There may also be a major problem of credibility. Over the years, at least in the United States, government spokesmen have not always been forthright in their reporting to the public on radiation matters. The threat of massive claims for compensation against certain federal agencies further tends to undermine the authority of government pronouncements on nuclear matters in general. In the post-Watergate, post-Irangate, post-Chernobyl atmosphere, many Americans appear to assume that public agencies and public officals are not above tampering with scientific evidence.

Government agencies must present research findings in their appropriate context, to explain the scientific processes by which the information was obtained, and to clarify the significance of the implied risks. The provision of context and perspective may be the most important contribution government can make. A truly informed public must be able to discriminate among various interpretations of the same set of facts and to appreciate the uses of scientific knowlege and the limits of certainty as applied to radiation.

3. The Use of Research Results to Protect the Public and Worker Health and Safety

Contrary to what might be assumed, there are essentially no direct pathways by which research results on the health effects in human populations exposed to low level radiation find their way to government officials responsible for setting radiation protection standards and regulatory policies.[31] Instead, results of research are communicated from the scientific community to the federal agencies needing it through a number of channels outside of the government that have become established over many years. One of these is the open peer-

reviewed scientific literature in which research investigators publish their findings regularly. Those who are responsible for radiation standards and regulatory policies are expected to keep abreast of this literature, to assess its individual quality, and to use rigorous scientific discrimination in its application to radiation protection philosophy.

There are other valuable pathways by which research results on the health effects of ionizing radiation may be transmitted to those needing them for public policy and decision-making: the reports of the International Commission on Radiological Protection[7,8] and the National Council on Radiation Protection and Measurements[10] and the reports of the National Academy of Sciences-National Research Council[1,2,16,19,20] and the United Nations Scientific Committee on the Effects of Atomic Radiation.[17,32,33,34,35] These nongovernmental organizations have for many years systematically drawn together expert research scientists both in the United States and throughout the world to review and examine the scientific literature and to write reports on an ever-expanding series of subjects and topics pertinent to protection from ionizing radiation, appropriate for its regulation, standards setting, and radiation protection philosophy. The International Commission on Radiological Protection and National Council on Radiation Protection and Measurements reports provide detailed information concerning safe operating practices as well as recommendations pertaining to radiation protection standards. The National Academy of Sciences-National Research Council reports, through comprehensive analyses of the scientific literature, have provided many useful summaries and interpretations of the health risks of ionizing radiation. Together, the International Commission on Radiological Protection, National Council on Radiation Protection and Measurements and National Academy of Science-National Research Council and the United Nations Scientific Committee on the Effects of Atomic Radiation provide another valuable feedback loop, transmitting research data to those responsible agencies concerned with public policy and decision-making on the control, regulation, and application of ionizing radiation in our society.

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References

1. *Health Effects of Exposure to Low Levels of Ionizing Radiations.* Report of the Committee on the Biological Effects of Ionizing Radiations (BEIR V Committee), NAS-NRC. Washington, D.C.: NAS, 1990.

2. *Health Risks of Radon and Other Internally Deposited Alpha-Emitters.* Report of the Committee on the Biological Effects of Ionizing Radiations (BEIR IV Committee), NAS-NRC. Washington, D.C.: NAS, 1988.

3. *Population Dose from X-Rays U.S. 1964.* U.S. Department of Health, Education, and Welfare, Bureau of Radiological Health Report, Public Health Service Publication no. 2001. Washington, D.C.: U.S. Government Printing Office, 1969.

4. *Radiological Health Handbook.* Compiled and edited by the bureau of Radiological Health and the Training Institute, Environmental Control Administration. Washington, D.C.: U.S. Government Printing Office, 1970.

5. *Population Exposure to X-Rays U.S. 1970.* Public Health Service x-ray exposrue study conducted under the direction of the Bureau of Radiological Health. Department of Health, Education, and Welfare Publication (FDA) 73-8041. Washington, D.C.: U.S. Government Printing Office, 1973.

6. *The Department of Energy Organization Act of 1977 (P.L. 95-91).* United States Congress, Washington, D.C.: U.S. Government Printing Office, 1977.

7. *Recommendations of the International Commission on Radiological Protection.* ICRP Publication 26. New York: Pergamon Press, 1977.

8. *Recommendations of the International Commission on Radiological Protection* (as amended 1959 and revised 1962). ICRP Publication 6. New York: Pergamon Press, 1964.

9. Eisenbud, M. *Environmental Radioactivity.* New York: McGraw Hill, 1989.

10. *Basic Radiation Protection Criteria.* NCRP Report 39. Washington, D.C.: NCRP, 1971.

11. *The Atomic Energy Act of 1946 (P.L. 79-585).*
United States Congress, Washington, D.C.: U.S. Government Printing Office, 1946.

12. *The Atomic Energy Act of 1954 (P.L. 83-703).*
United States Congress, Washington, D.C.: U.S. Government Printing Office, 1954.

13. *U.S.-Japan Joint Reassessment of Atomic Bomb Radiation Dosimetry in Hiroshima and Nagasaki.* Roesch, W.C. (ed.). Radiation Effects Research Foundation, Vol. 1, Hiroshima, Japan: RERF, 1987.

14. The Radiation Effects Research Foundation (formerly ABCC) was established in April 1975 as a private nonprofit Japanese Foundation, supported equally by the Government of Japan through the Ministry of Health and Welfare, and the Government of the United States through the National Academy of Sciences under contract with the Department of Energy.

15. *The Biological Effects of Atomic Radiation.* Summary Reports from a Study by the National Academy of Sciences. Washington, D.C.: NAS, 1956, 1963.

16. UNSCEAR 1969, 1966, 1964, 1962, 1958. Report of the United Nations Scientific Committee on the Effects of Atomic Radiation. General Assembly, Official Records. 1969, 24th sess., supp. no. 13 (A/7613); 1966, 21st sess., supp. no. 14 (A/6314); 1964, 19th sess., supp. no. 14, (A/5814); 1962, 17th sess., supp. no. 16 (A/5216); 1958, 13th sess., supp. no. 17 (A/3838). New York: United Nations, 1969, 1966, 1964, 1962, 1958.

17. *Background Material for the Development of Radiation Protection Standards.* Federal Radiation Council Report No. 2. Washington, D.C.: U.S. Department of Health, Education, and Welfare, 1961.

18. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation.* Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR I Committee), NAS-NRC, Washington, D.C.: NAS, 1972.

19. *Considerations of Health Benefit-Cost Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives.* Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR II Committee), NAS-NRC, Washington, D.C.: NAS, 1977.

20. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation.* Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR III Committee), NAS-NRC. Washington, D.C.: NAS, 1980.

21. *Radiation Protection Guidance for Diagnostic X-Rays.* Report of the Interagency Working Group on Medical Radiation, United States Environmental Protection Agency. Federal Guidance Report No. 9 EPA 520/4-76-019, 1976.

22. *Radiological Quality of the Environment in the United States*, 1977, ed. K.L. Feldman, United States Environmental Protection Agency Report EPA 520/1-77-009. Washington, D.C.: EPA, 1977.

23. *Provisions for Hazardous Waste Regulation and Land Disposal Controls under the Resource Conservation Act of 1976.* Summary (SW-644) prepared by the Office of Solid Waste, United States Environmental Protection Agency, 1978.

24. *The Energy Reorganization Act of 1974 (P.L. 93-438).*
United States Congress, Washington, D.C.: U.S. Government Printing Office, 1974.

25. *The Federal Nonnuclear Energy Research and Development Act of 1974 (P.L. 93-577).* United States Congress, Washington, D.C.: United States Government Printing Office, 1974.

26. *Standards for Protection Against Radiation.* United States Nuclear Regulatory Commission rules and regulations. *Code of Federal Regulations, Title 10, Part 20.* Washington, D.C.: USNRC, 1979.

27. *AEC Licensing Guide, Medical Programs.* Division of Materials Licensing, United States Atomic Energy Commission. Washington, D.C.: U.S. Government Printing Office, 1965.

28. *A Review of the Department of Transportation (DOT) Regulations for Transportation of Radioactive Materials.* Compiled and edited by A.W. Grella. Washington, D.C.: Department of Transportation, Office of Hazardous Materials, 1977.

29. *A Guide for Preparation of Applications for Medical Programs.* NUREG 0338 (Draft). Prepared by Radioisotopes Licensing Branch, Nuclear Regulatory Commission, Washington, D.C.: NRC, 1976.

30. *Research in Progress: FY1988.* Summaries of Projects Sponsored by the Office of Health and Environmental Research, Office of Energy Research, DOE/ER-0185/4, Washington, D.C.: United States Department of Energy, 1988.

31. *Reactor Safety Study. An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants.* Study sponsored by the U.S. Atomic Energy Commission and performed under the independent direction of Professor Norman C. Rasmussen of the Massachusetts institute of Technology. United States Nuclear Regulatory Commission Report WASH-1400 (NUREG 75/014), Washington, D.C.: NRC, 1975.

32. *Sources and Effects of Ionizing Radiation.* United Nations Scientific Committee on the Effects of Atomic Radiation. Report E. 77. IX. 1. 1977 Report to the General Assembly, with annexes. New York: United Nations, 1977.

33. *Ionizing Radiation: Sources and Biological Effects.* United Nations Scientific Committee on the Effects of Atomic Radiation. Report E. 82. IX. 8. New York: United Nations, 1982.

34. *Genetic and Somatic Effects of Ionizing Radiation.* United Nations Scientific Committee on the Effects of Atomic Radiation. Report A/41/16. New York: United Nations, 1986.

35. *Sources, Effects and Risks of Ionizing Radiation.* United Nations Scientific Committee on the Effects of Atomic Radiation. Report E. 88. IX. 7. New York: United Nations, 1988.

LAWRENCE BERKELEY LABORATORY
TECHNICAL INFORMATION DEPARTMENT
1 CYCLOTRON ROAD
BERKELEY, CALIFORNIA 94720