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CONTENTS

On the cover: A truck loaded with scrap metal passes through a gamma detector to avoid potential contamination in recycled materials. See article by A. Clouvas et al. on page 154 for more information.

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A REVIEW OF THE HISTORY OF U.S. RADIATION PROTECTION REGULATIONS, RECOMMENDATIONS, AND STANDARDS

Cynthia Gillian Jones*

Abstract—**Shortly after the discovery of x rays by Wilhelm Konrad Roentgen in 1895, and the isolation of the element radium by Pierre and Marie Curie three years later, the fascination with and potential for an array of uses of ionizing radiation in medicine, science, and technology was born. As with any new technology, there was a need to balance both the beneficial and potential detrimental effects of uses of these new technologies for the advancement of humankind. In the early days, radiation hazards were not well understood. Over the decades increasing concerns in the scientific community and lay population demanded that standardized guidance and recommendations be developed for the use of ionizing radiation. Today, U.S. radiation protection standards and recommendations to protect the occupational worker, members of the general public, and the environment are numerous and complex. This review summarizes the history of the development and application of radiation protection standards and regulations to assure the safe use of radiation and radioactive materials. The evolution and roles of international and national scientific recommending and regulatory organizations that shape U.S. radiation protection policy are described and discussed.**

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Key words: historical profiles; safety standards; regulations; reviews

INTRODUCTION

Interest in the new twin discoveries of x rays in 1895 and radioactivity in 1896, as described by Kathren (1962, 1996) (Roentgen 1895, 1896; Bequerel 1896; Thompson 1896; Schubert and Lapp 1957; Mould 1980; Vetter 1991), excited the world as their applications became more widespread. Roentgen's discovery of x rays was followed a few months later in 1896 by Henri Becquerel's discovery that certain uranium salts gave off penetrating rays. This strange behavior of uranium prompted Marie and Pierre Curie to separate the substance responsible for emitting the radiation that Becquerel had discovered. Madame Curie named this emission "radioactivity" to describe the spontaneous activity that she observed after wrapping large quantities of uranium salts in paper, which showed the same effects as x rays on photographic plates (Becquerel and Curie 1901; Curie 1949; Schubert and Lapp 1957; Frame 1996). These new discoveries fascinated the public as well as the media, generating many newspaper and magazine articles suggesting that radium could be useful for arthritis, fertilizer, and as the great cure for cancer.

Although scientists and physicians had yet to realize the full potential of the effects of ionizing radiation for either x rays or radium, the many prescribed uses by those entering the field of radiation treatment yielded vastly different consequences. Unlike x rays, which posed an external threat mostly to the skin of the individuals exposed, radium caused its greatest harm through internal ingestion or injection. Although the radiation effects of excessive radium exposure, such as skin ulcerations, appeared in a relatively short period of time (hours to days) in affected patients, the long-term damaging effects of radium did not appear for a latent period of several years to decades. Due to the vast number of people entering the field and experimenting with this new technology, it quickly became apparent that exposure to large amounts of radiation could have deleterious biological effects on the human body. Even Thomas A. Edison, the famous inventor and early x-ray enthusiast, became disillusioned with the technology after experiments with x rays in the early 1900's rendered him with irritated eyes and a fellow scientist in his laboratory became seriously ill and later died from his acute exposure to x rays (Schubert and Lapp 1957; Walker 2000). By 1910, many physicians, radiologists, and technicians handling radium preparations and/or x-ray equipment began to develop and report skin irritations and ulcerations, ultimately leading to premature skin cancer. By 1911 at least 94 cases of apparent x-ray

* U.S. Nuclear Regulatory Commission, Office of Nuclear Security and Incident Response, Mail Stop T4-D22A, Washington, DC 20555.

For correspondence or reprints contact: the author at the above address, or e-mail at cgj@nrc.gov.

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induced skin carcinomas and sarcomas were reported and scientists concluded that exposure to radiation could cause sterility, bone disease, and cancer (Hesse 1911; Kathren 1996). In these early years, there were no standardized methods for the measurement of radiation exposure or the calculation of radiation dose, although some efforts were initiated to standardize and formalize quantities and units associated with radioactivity. It was not until 1925, however, that an investigation conducted by a New Jersey Medical Examiner, Harrison S. Martland, suggested that evidence linking the ingestion of radium by female factory workers could lead to serious illness and death (Clark 1997; Walker 2000). It was Martland's discovery concerning the dangers of internally-deposited radionuclides that joined the concerns regarding health effects of x rays from external sources as strong incentives for protection against radiation hazards (Martland et al. 1925; Walker 2000).

EARLY RECOMMENDATIONS (1928–1945)

After the use of both x rays and radium in the medical profession became widespread before the end of the 19th century, it became apparent to scientists and physicians that exposure to large amounts of radiation could cause serious illness in humans. Kathren and Ziemer (1980) believed that the decades between 1928 and 1948 were a period when radiation protection emerged as a science in its own right due in large part to the many concerns regarding the health effects from exposure to radiation.

As these new radiation technologies became widespread, the need for sharing information and advancing technology regarding the subject of radiation protection among radiologists and scientists in several countries led to a series of meetings held at the First and Second International Congress of Radiology. In 1928, this Congress approved the formation of the International Advisory Committee on X-Ray and Radium Protection, later called the International Commission on Radiological Protection (ICRP), to study the problems of ionizing radiation (Taylor 1958a, 1958b, 1979; Brodsky et al. 1995). In 1929, the American Medical Association entered the growing list of medical associations to pass a resolution condemning the use of x rays to remove body hair, and three years later it withdrew radium from its list of remedies approved for internal administration (Walker 2000).

To present a unified position by the United States on various aspects of radiation safety, the American Roentgen Ray Society, the Radiological Society of North America, and the Radium Society agreed in 1929 to consolidate their efforts in this area and established a national Advisory Committee on X-Ray and Radium Protection (Taylor 1981). This national Advisory Committee was a consolidation of several radiation protection committees then existent in the United States (Taylor 1971a, 1971b). Membership consisted of radiologists, physicists, and representatives from industry. Although some of the members were government employees, they served on the committee because of their necessary expertise as private individuals. Lauriston S. Taylor (1958a, 1958b) describes in great detail the effects of this committee, the National Bureau of Standards (NBS), and the history associated with his responsibility to organize and later chair this national Advisory Committee that developed and formulated the U.S. view analogous to the view of the ICRP. The approach throughout this whole period was largely toward limiting the exposure of radiological workers to levels of radiation that seemed to result in no visible effects, since concepts and techniques for assessing radiation dose were in their infancy (Taylor 1988).

By the mid-1920's, the primary difficulty that faced the radiation protection community was the need to recommend a level of radiation exposure that did not cause an observable injury. After much study of observable effects in humans, in 1934, both the national and international radiation protection communities concluded that they had a sufficient technical basis to recommend both a whole body "tolerance dose" of radiation [0.2 R (roentgen) per day (25 R y^{-1})] and a separate finger dose of 5 R per day limit for individuals that were occupationally exposed to x rays.[†] The tolerance dose was considered to be that level of radiation to which an individual could be continuously exposed without any demonstrable ill health effect or harm. This represented the first generally accepted dose from which developed a systematic approach to the standardization of radiation protection limits. As described by Walker (2000), while the national Advisory Committee on X-Ray and Radium

[†] The first standard for radiation workers was expressed in a directly measurable form. Based on the information available in 1934, the threshold erythema dose was 550 roentgen (R). (Note: in the 1930s, dose was expressed in units of the roentgen, symbolized by R, which for photon radiation is approximately equivalent to a cSv).

Throughout this article, if the referenced radiation units were originally issued in older, English units (e.g., rem), then SI units are indicated in parenthesis. However, if the original units were issued in SI units (e.g., Sv), then English units are followed in parenthesis. To derive a standard for tolerance dose, this erythema threshold was rounded off to 600 R. In 1925, A.M. Mutscheller in the U.S., and R.M. Sievert in Sweden, independently had suggested that an exposure one-tenth of a threshold erythema dose per year "would be acceptable for those working with x rays (or radium)." Based on the assumption that there are 250 working days per year, this one-tenth dose converts to ~0.2 R d^{-1} (NBS 1934). But because of uncertainties in the erythema dose and the conversion from dose into R, the Advisory Committee decided to round down the exposure to 0.1 R d^{-1}, which was the acceptable standard for several years.

Protection recognized that exposure to radiation may be detrimental, they considered the levels below the tolerance dose to be generally safe and unlikely to cause permanent damage to an average individual (Walker 1989). As Kocher (1991) noted, the tolerance dose was strictly defined only for x rays, although later the dose limit was found to be also satisfactory for exposure to more penetrating high-energy photons.

The Advisory Committee on X-Ray and Radium Protection issued several reports on x-ray protection (NBS 1931, 1936) and for radium protection by 1934 and 1938 (NBS 1934, 1938). In 1941, this national Advisory Committee also recommended a tolerance dose for hazards from internally deposited radionuclides, specifically for radium and its decay products, including radon (Evans 1981; Taylor 1971a, 1971b). Although much of the radium in use at the time was primarily for medical therapy applications, the U.S. Navy also used it for several industrial applications, including watch dials and instrument panels for aircraft. The Navy later requested the national Advisory Committee to study the issue and publish recommended maximum "body burdens" for radium (NBS 1941). As Kocher (1991) describes, the recommended limit for a body burden was 0.1 μCi (4 kBq) of radium which was based primarily on observed radiation injuries in radium dial painters with residual body burdens of about ten times this limit, or 1 μCi (40 kBq). As Evans (1981) noted, radiation experts at the time believed that the recommended dose for radium and radon provided an ample margin of safety for the relatively small number of persons exposed to occupational radiation. As described by Taylor (1971a, 1971b), it was this limit on the radium body burden that provided the basis for control of exposure of workers to plutonium during the Manhattan Project during World War II (Taylor 1971a, 1971b). These limits for internal exposure later served as the foundation for ICRP and NCRP recommendations on maximum permissible body burdens for all bone seeking radionuclides (ICRP 1959b; NBS 1953; NCRP 1953). Internationally, ICRP recommended a slightly higher tolerance dose [5.2×10^{-5} C $kg^{-1}d^{-1}$ (0.2 R d^{-1})] for exposure of workers to x rays which corresponds to the current annual dose equivalent to the skin of about 0.5 Sv (50 rem). Thus, it appears that the principal biological endpoint of concern from high exposures of the skin and the required dose limit appear to have been correctly assessed over 70 years ago (Kocher 1991).

DEVELOPMENT OF RADIATION PROTECTION RECOMMENDATIONS (1945–1959)

After the world's first atomic explosions in Hiroshima and Nagasaki in 1945, radiation protection became a more complicated task. Whereas before this time, the predominant practical experience came from medical and industrial applications resulting from experience with x rays and radium, the new era of nuclear fission and later fusion introduced a vast array of new radionuclides into the health physicist's profession. It was because of this new atomic age that in 1946 the national Advisory Committee on X-Ray and Radium Protection recommended that its charter be expanded and be renamed the National Committee on Radiation Protection, which later became the National Committee on Radiation Protection and Measurements (NCRP) to indicate more fully the ranges of its interests. Healy (1988) speculates that after World War II, the NCRP recognized the need for reconsidering all aspects of their previous recommendations since much had changed from the prewar period when only x rays and gamma rays from radium exposure to a limited population of workers were the primary causes of radiological concern. NCRP designated Lauriston S. Taylor its first chairman. He was serving as chair of its predecessor national Advisory Committee, a post he had held since 1929.

In the United States, congressional and military leaders engaged in a debate over whether atomic energy would be controlled by the country's military or its civilian government. The legislature at the time took the optimistic view that atomic energy should be used not only for defense, but to promote peace, improve the public welfare, and encourage open competition in private enterprise (GSG 2000).

After long months of debate and controversy, President Harry S. Truman agreed to resolve the issue and signed the Atomic Energy Act of 1946 (The McMahon Bill), which established a new Federal agency, the Atomic Energy Commission (AEC) to manage the nation's atomic energy program (McMahon 1946). Under Executive Order 9816, all personnel and properties, such as fissionable materials, atomic weapons, data, contracts, patents, discoveries, and facilities directed to perform atomic energy research were transferred to the AEC (E.O. 9816). While the AEC had considerable freedom in hiring scientists and professionals who could effectively staff these programs, the high security risks associated with nuclear scientific and industrial facilities dictated that they remain government-owned. Indeed, the McMahon Bill focused on and ensured that the security and control of strategically important materials related to, or arising from, the development of nuclear weapons would remain under the Federal government's jurisdiction. Worker and public health and safety, as promulgated much later in the more familiar Atomic Energy Act of 1954 and later amendments, were not a major consideration of the McMahon Bill. In fact, the word "safety" is mentioned in the McMahon Bill only four times, none

with regard to radiation safety. The fundamental definitions of source, byproduct, and special nuclear material are essentially unchanged from how they were first defined in the McMahon Bill. They were clearly based on the desire to control materials of strategic value to the development of nuclear weapons and materials produced in the use of such strategically valuable materials, not on the inherent radiological hazards.

As the AEC was established, the national and international radiation protection recommending bodies began to reform their concept of "permissible dose" to take the place of "tolerance dose" for the ever-expanding number of workers (NCRP 1954). In addition, NCRP recommended that the maximum permissible dose to the gonads and blood-forming organs be 0.3 rem (3 mSv) per week. This corresponded to a limit on annual whole body dose equivalent of 0.15 Sv (15 rem). The reduction in dose limits for external exposure was prompted by three considerations: (1) concern for the genetic hazard from radiation exposure; (2) an observed excess leukemia prevalence among early radiologists; and (3) the development of the nuclear weapons industry with increased potential for exposures of workers to sources of high-energy photons that could easily penetrate the tissues of the body (UNSCEAR 1964; Kocher 1991). Kathren (1996) states that the prevailing belief underlying the tolerance dose was that there was a threshold dose that needed to be exceeded if any effects—early or late—were to occur. Another principal argument, as described by Taylor in 1988, was that the concept of a tolerance dose "might carry improper implications of safety" (Taylor 1988). We can see the same type of argument today, against the use of the terms permissible, acceptable, *de minimis*, or "Below Regulatory Concern" doses, which continues to be used to the detriment of the radiation protection community as suggested terminology that could imply something other that total or absolute safety.

In January 1947, the AEC officially took over the functions of the Manhattan Engineering District Project, which had built the first atomic bombs during World War II. With the AEC now conducting tests of atmospheric nuclear weapons in the Pacific, and later in Nevada, there was growing concern that radiation fallout from these weapons could reach every person in the world (Taylor 1980a, 1980b). In addition, earlier fruit fly experiments and findings of H.J. Muller and other geneticists indicated that reproductive cells were especially vulnerable to even small amounts of radiation and that mutant genes could be inherited from a parent with no obvious radiation-induced injuries (Walker 2000). With the potential for many non-occupationally exposed individuals to be exposed to radiation fallout, it gradually became evident to the AEC that regulations were needed to limit radiation exposure to the public. As an aside, it is interesting to note that protection of the general public had not been an issue in the earlier system of radiation protection because of the assumption of a tolerance dose and that the number of facilities that could cause exposure to members of the public were relatively few and fairly isolated. Until 1945, there had been little concern about the military uses of atomic weapons, but relatively little concern about radiation as it might affect public safety (Taylor 1980a, 1980b). Walker (2000) describes that additional concerns of fallout also prompted great debate and had an important and immediate impact on radiation protection in three ways. First, was to increase the public awareness and concern about the risks of exposure to ionizing radiation. Second, the credibility of the AEC as a guardian of both public health and the atomic weapons programs came into serious question. And third, the public controversy of restricting all radiation exposures (that from x rays and fallout) "as low as possible," motivated the NCRP and the ICRP to further reassess and lower its radiation protection recommendations. Consequently, in devising a new proposed system of radiation protection, an indirect method of limiting minors to one-tenth that of the workers was chosen. As described by Healy (1988), because of the widespread distribution of those under age 18, this would control doses to the public in all but the most unusual situations.

In President Dwight D. Eisenhower's "Atoms for Peace" speech in 1953, the President proclaimed that the atomic age had "moved forward at such a pace that every citizen of the world should have some comprehension, at least in comparative terms, of the extent of this [atomic warfare] development of the utmost significance to every one of us" (Eisenhower 1953). Because of the continued growth of the stockpile of atomic weapons in the years after World War II, President Eisenhower recommended to the United Nations General Assembly that governments involved in a nuclear weapons program should begin to make joint contributions from their stockpiles of uranium and fissionable materials to an international atomic energy agency which would establish an acceptable system of world-wide nuclear material inspection and control (Eisenhower 1953; United States Congress 1955). This agency, now called the International Atomic Energy Agency (IAEA), was established in 1957, as part of the United Nations (U.N.). The IAEA works with its Member States and multiple partners worldwide to promote safe, secure, and peaceful nuclear technologies. In addition, the General Assembly of the U.N. adopted a resolution in December 1955, establishing a U.N. Scientific Committee on the Effects of Atomic Radiation, commonly known as UNSCEAR (UNSCEAR 1958).

Due to the number of new scientific recommendations and interest by Congress and the public regarding radiation and the effects of radioactive fallout, the AEC, in 1955, requested the National Academy of Sciences-National Research Council (NAS/NRC) to undertake a major study of the effects of low-level radiation. Although not directly involved in setting radiation protection standards, the NAS/NRC appointed a Committee on the Biological Effects of Atomic Radiation, which became known as the BEAR Committee (NAS/NRC 1956). Years later, this Committee would be renamed as the Biological Effects of Ionizing Radiation (BEIR) Committee. In addition, the NCRP and ICRP cooperatively worked with the BEAR Committee and also undertook extensive evaluation of the concerns associated with population exposure from fallout, especially with respect to genetic effects. Although different groups conducted these studies, they arrived at essentially the same conclusions because the database was the same for all and there was membership overlap between the organizations. More specifically, they agreed that there could be possible genetic consequences of exposing the entire population to both medical and occupational sources. The BEAR Committee's first report, titled, "The Biological Effects of Atomic Radiation," was issued in 1956, and, as a result, raised questions and widespread concern about the genetic effects of radiation (NAS/NRC 1956). The BEAR report stated that exposure to radiation, even in small doses, could cause genetic consequences that could be serious in individual cases and potentially harmful over a lifetime for the entire population. It emphasized that genetic mutations that resulted from radiation exposure would be expressed later in life as latent genetic effects and result in increased radiation risk for future generations (NAS/NRC 1956).

During these deliberations regarding potential latent radiation health effects and new uses for atomic energy, the ICRP also began changing its philosophy concerning the lowering of its recommendations for lifetime dose and establishing new exposure recommendations for the public. Prior to 1956, ICRP's permissible levels of exposure to ionizing radiation had been expressed in terms of a dose over a rather short interval of time (1 d or 1 wk). Implicitly, it was assumed that this average dose rate was low enough so that no appreciable bodily injury would become apparent in the lifetime of the individual (ICRP 1958). The basic permissible dose to a worker at the time was 0.3 rem (3 mSv) per week. Assuming that a person was occupationally exposed at this rate (50 weeks a year), for 50 y, the permissible whole body accumulated dose would be 750 rem (7.5 Sv). However, after significant public and international debate concerning the lasting effects of ionizing radiation, the ICRP held several meetings in 1950, 1952, and 1956, to consider revising its previous recommendations. In fact, ICRP had already included a warning in its 1955 report, because the value of 750 rem (7.5 Sv) constituted a "large" lifetime dose (ICRP 1958). Consequently, in April 1956, the ICRP adopted changes to its system that corresponded to a three-fold decrease in weekly dose and recommended inclusion of dose limits to a number of critical organs, including the gonads, lens of the eye, and the blood-forming organs. The resulting recommendations included an accumulated dose limit to the critical organs of 5 rem (50 mSv) per year and a quarterly limit of 3 rem (30 mSv) in any 13 consecutive weeks (NCRP 1957; ICRP 1958). This later recommendation to have "consecutive" weeks was added to ensure that operations were carried out in such a way that intermittent doses approximating the full 13-wk quota did not occur at short intervals.

When finalized, these ICRP recommendations conformed to the recommendations published in the 1956 BEAR report in keeping radiation exposures "as low as possible." In addition, ICRP also specified total permissible accumulated doses to workers at various ages: 50 rem (0.5 Sv) up to age 30 y; 100 rem (1 Sv) to age 40 y; and 200 rem (2 Sv) lifetime dose to age 60 y. NCRP also issued similar recommendations for radiation exposures in 1958, but added the flexibility and a formula to adjust the amount of occupational exposure corresponding to age. In its recommendations, NCRP provided for a maximum permissible dose (MPD) to the most critical organs (whole body, head and trunk, active blood-forming organs, or gonads) to not exceed 5 rem (50 mSv) multiplied by the number of years beyond age 18 y, and the dose in any 13 consecutive weeks could not exceed 3 rem (30 mSv) or 12 rem (120 mSv) per year. Thus, the MPD formula became equal to $5(N-18)$, where N was equal to a person's age, with a maximum of 12 rem (120 mSv) per year (NCRP 1958).

Recommendations for exposure limits for the public were also being developed by ICRP and NCRP in the mid- to late-1950's. In 1954, the ICRP recommended that the exposure limits for the public should be one-tenth of the limits for radiation workers (ICRP 1955). This reduction was based on risk-benefit considerations as to whether exposure limits for the public should be lower because the public receives no direct benefit in association with their exposures (Taylor 1979; Kocher 1991). On the basis of the 1949 ICRP recommendations on maximum permissible dose to workers, the first recommended limit for an individual member of the public was an annual dose of 1.5 rem (15 mSv). In 1957,

NCRP similarly recommended a limit to "persons outside of controlled areas" of 0.5 rem (5 mSv) (NCRP 1958). This was one-tenth of the dose limit for workers that NCRP introduced in 1956. While both the ICRP and NCRP issued public dose recommendations at this time, they stressed that they did not intend that these revisions be applied to fallout from weapons testing because this source of exposure could not be controlled in the same manner as releases from nuclear facilities (Kocher 1991).

During all of the debate concerning revised recommendations for radiation protection, in July 1955, the AEC issued proposed general standards for public comment regarding the protection of licensees, their employees, and the public against radiation hazards from the possession or use of source, special nuclear, or byproduct material under any license issued by the AEC (AEC 1957). After the collection of public comments, including those from the ICRP, NCRP, and the BEAR Committee, in 1957, the AEC published its revised standards for public comment in Title 10, Atomic Energy, Part 20 (10 CFR Part 20), "Standards for Protection Against Radiation" (AEC 1957). These standards agreed substantially with NCRP's first official published report in 1953 of its Subcommittee on Permissible Internal Dose, Handbook 52, "Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water" and NBS Handbook 59, "Permissible Dose from External Sources of Ionizing Radiation" (NCRP 1953, 1958). When it was published on 29 January 1957, the entire *Federal Register* notice for all of 10 CFR Part 20 was a total of six pages, including the Appendix A for permissible weekly doses and Appendix B for permissible concentrations of radionuclides in air and water. As explained at the time, these recommended dose limits to blood-forming organs, gonads, or lens of eye could not exceed either 0.9 rem (9 mSv) in any 7 consecutive days or 3 rem (30 mSv) during any 13-wk period. These limits were based on the assumption that the occupational exposure would continue throughout the working life of the individual and that environmental exposures, once received, would continue over a lifetime (NCRP 1953).

Special units of radiation measurement and concepts for internal models were also established at this time. The "critical organ" concept was established in 1959 and was based on four factors: (1) the organ that accumulates the greatest concentration of the radioactive material; (2) the indispensability of the organ to the well being of the entire body; (3) the organ damaged by entry of the radionuclide into the body; and (4) the radiosensitivity of the organ (NBS 1959; NAS/NRC 1959). One week was chosen as the period over which the doses could be averaged since this represented a reasonable amount of time that individual dosimeters, such as film, could be easily processed (Healy 1988). Critical organs that were chosen were the skin (based upon previous erythematic cases involving skin cancer) and bone (blood-forming organs) to avoid leukemia. Special units such as the "rad," which describes the amount of absorbed radiation dose to 100 ergs per gram of human tissue, gained preference over the previous term "roentgen" (Mazuzan and Walker 1997). Although there is widespread belief that the term "rad" is an acronym for "radiation absorbed dose," it was not identified by the International Commission on Radiation Units (ICRU) as an acronym, and as suggested by Dr. Lauriston Taylor, Chairman Emeritus of the ICRU, "the term rad was simply suggested as a word by itself" (Taylor 1990; Frame 2000). The other unit, the "rem," an acronym for "roentgen equivalent man" replaced the earlier term, "rep" (roentgen equivalent physical) and was applied to the radiation dose equivalent to incorporate the relative biological effectiveness of x ray, alpha, beta, gamma, and neutron radiation.

CONGRESSIONAL INTEREST AND FORMULATION OF THE FEDERAL RADIATION COUNCIL AND THE NCRP (1959–1974)

In 1957, the Congressional oversight committee of the AEC, the Joint Committee on Atomic Energy, held public hearings on "The Nature of Radioactive Fallout and its Effects on Man," and, in 1959, on "Employee Radiation Hazards and Workman's Compensation," "Industrial Radioactive Waste Disposal," and "Biological and Environmental Effects on Nuclear War" (JCAE 1957, 1960; FRC 1960). During the course of these hearings, it was realized that despite the Federal Government's basic responsibility for radiological safety, the Atomic Energy Act's setting of radiation protection standards (although not their implementation), was in the hands of private organizations, more specifically the ICRP and the NCRP. At the time, there was no official agency within the Executive branch of the U.S. Government assigned the responsibility for the formulation of radiation protection standards or guidance for all Federal agencies. Each agency was free to formulate whatever standards it deemed necessary within the bounds of its radiation protection responsibilities (Palmiter 1966).

Because of this omission and of growing concerns over radioactive fallout, in 1959, President Eisenhower issued Executive Order 10831 and Public Law 86–373 to create the Federal Radiation Council (FRC or Council) whose responsibility was to "... advise the President with respect to radiation matters, directly or indirectly,

affecting health, including guidance for all Federal agencies in the formulation of radiation standards," (JCAE 1959; FRC 1960; Mills et al. 1988). As described by Palmiter and Tompkins (1965), who were the special assistant and Executive Director, respectively, of the FRC, the establishment of the Council followed an extensive study performed by the Bureau of the Budget in cooperation with the Chairman of the AEC. This study reviewed the Federal Government's radiation protection programs, problems related to fallout from nuclear weapons testing, and the position of the Executive branch of the government concerning the development of a policy for radiation protection. The FRC consisted of the Secretaries of Agriculture, Health, Education and Welfare (now Health and Human Services, HHS), Defense, Labor, Commerce, and the Chairman of the AEC (Mills et al. 1988). Section 274(h) to the Atomic Energy Act was added, and required, among other things, that, "the Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, and the Chairman of the NCRP. . . " (FRC 1960). While the FRC was not a regulatory body and did not have binding authority over Federal agencies, it did have the authority to act as an advisory body on issues regarding radiation protection. It also required Federal agencies to provide the FRC with an annual report on the development and promulgation of rulemaking or operating criteria related to radiation protection guidance promulgated by the President (Palmiter and Tompkins 1965).

NCRP, meanwhile, had continued to evolve over the years and began to interact more with Congress following the debates on radiation fallout in the early 1960's. From 1929 to 1959, reports from the NCRP had been published as part of the NBS Handbook Series, which gave the impression that these reports represented official U.S. government recommendations, even though they were actually those of an independent body having no legal authority. However, by the late 1950's, a great deal of public attention was directed at radiation protection standards. As a result, the NBS Director became concerned about publication of NBS reports containing biomedical material for which criticism could be leveled for publishing reports without adequate medical review (Taylor 1971a, 1971b). For this and others reasons, the NCRP decided to separate from the NBS and to seek a Federal charter through the U.S. Congress. In 1964, that charter was enacted as Public Law 88-376, and the word "Committee" was changed to "Council" making the official name the National Council on Radiation Protection and Measurements (P.L. 88–376). This Public Law designated NCRP as a corporation to collect, analyze, and disseminate in the public interest, information and recommendations about: (1) protection against radiation; and (2) radiation measurements, quantities and units (P.L. 88–376). As part of its charter, NCRP was to work cooperatively with the ICRP, FRC, ICRU, and other national and international organizations including Federal agencies and private sector companies concerned with quantities, units, and measurements associated with radiation protection.

In 1960, the FRC issued its first Federal recommendations, called Radiation Protection Guides (RPGs), on occupational and population radiation exposures. For radiation workers, the annual dose limit to the whole body was five times the number of years beyond age 18, with a quarterly RPG of 3 rem (30 mSv). Additional guidance was specified for the skin of the whole body, thyroid, extremities, bone, and other organs (Mills et al. 1988). For the general population, the individual limit was 500 mrem (5 mSv) per year to the whole body and a separate limit to the average population of 5 rem (50 mSv) over 30 years to the gonads (U.S. EPA 2000). This whole body individual dose limit of 0.5 rem (50 mSv) was selected so as to assure that the average gonadal exposure guidance of 5 rem in 30 years would not be exceeded.

FRC also issued guidance in the area of radon in uranium mines to protect miners from radiation-induced lung cancer. In issuing this guidance, the FRC established two terms called the Working Level (WL), which was defined as any combination of radon progeny in 1 L of air that would result in the emission of 1.3×10^5 MeV of potential alpha energy, and one Working Level Month (WLM), which was defined as the inhalation of air containing radon progeny concentrations of 1 WL for 170 h (FRC 1969). FRC determined that a standard of 4 WLM per year would adequately protect miners and would not have a severe impact on the underground uranium mining community, provided that additional time would be allowed for compliance in certain instances. Although the FRC also issued guidance on a number of other radiation protection issues, including internal radiation and diagnostic x-ray exposures, the general guidance for the public, as issued in 1960, has remained essentially unchanged.

In the late 1960's, Congress focused its attention on another radiation protection issue presented by the increasing number of newly manufactured television sets and machine uses of radiation by passing the Radiation Control for Health and Safety Act in 1968 (P.L. 90–602). This Act directed the Food and Drug Administration (FDA) to be the agency responsible for maintaining a national program to protect the public health from unnecessary emissions from machines that produce radiation. FDA established a program of mandatory and

voluntary standards to promote the safe and effective design and use of electronic products by minimizing the radiation emitted (FDA 1973). FDA's electronic product radiation control program included the development and administration of performance standards to measure and control the emission of electronic product radiation from electronic products. For further information concerning the development of these standards, Little (1980) discusses the process by which FDA's electronic product radiation safety standards and recommendations were developed and implemented.

After passage of the National Environmental Policy Act (NEPA) in 1969, many environmentalists and activists became concerned with future environmental issues associated with nuclear power production such as high-level waste and thermal pollution, and charged that these issues should also be addressed by the AEC in its licensing process of nuclear power plants (NEPA 1970; GSG 2000; Walker 2000). In response to NEPA, the AEC attempted to strike a balance between the requirements for environmental protection and its responsibilities in the power reactor licensing process. As a result, NRC issued an interpretation of its responsibilities under NEPA, which aroused the protests of environmentalists and prompted legal action by them (Walker 1992).

As the U.S. demand for cheap and abundant energy was beginning to wear on the economy, the environmental regulatory arena also began to change. In addition to the passage of NEPA in 1969, in December 1970, President Nixon announced the abolishment of the FRC as part of a general reorganization of Federal government programs. Its functions were transferred to a new Federal agency, the Environmental Protection Agency, (EPA), under Reorganization Plan No. 3 (Nixon 1970). This reorganization consolidated the environmental protection functions of several agencies and departments into the newly formed EPA. The activities of the EPA were to include four main areas regarding radiological protection:

1. Collection and analysis of radiation exposure data, including those from natural background radiation, medical practice, occupational exposures, and radioactive fallout;
2. Re-examination of the scientific bases used to estimate the risks associated with exposures to different quantities of radiation;
3. Re-examination of the various benefits derivable from activities associated with exposure to radiation and how these can be judged; and
4. Derivation of appropriate balances between benefits and risks.

EPA was also responsible for regulating hazardous materials in specific environmental media through several statutes issued subsequent to its formation. The most notable statutes, such as the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), provided EPA with considerable expanded authority for regulating both chemical and certain radiological hazards under the same legislative requirements (CAA 1970; SDWA 1970; CERCLA 1980; U.S. EPA 2000). Although EPA was generally provided research, monitoring, standard-setting, and enforcement authority for each category of pollutant, the transfer of radiation protection responsibilities was more limited than any other pollutant, in that the authority for enforcement of radiation standards was retained by the AEC (U.S. EPA 2000). The EPA assumed authority for radiation standards outside the boundaries of nuclear facilities, but the precise division of duties between the EPA and the AEC remained ill-defined (Walker 1992). In later years, EPA did gain enforcement authority for the regulation of some radioactive materials under various environmental statutes and developed a comprehensive set of standards addressing environmental issues for all phases of the uranium fuel cycle, including: uranium milling, chemical conversion; fuel fabrication and reprocessing; waste management, storage, and disposal; and site cleanup for milling operations. With the formulation of EPA, two key radiation protection functions were now in a single agency—the promulgation of generally applicable environmental standards and the development of national radiation protection guidance for Federal and State agencies.

In the summer of 1970, the FRC (whose activities have since been transferred to the EPA), asked the National Academy of Sciences to undertake a review and re-evaluation of the scientific knowledge concerning the effects on humans to exposure to ionizing radiation, including the shape of the low-dose response curve (NAS/NRC 1972). This was especially important at the time, since growing controversy and protests about the growth of nuclear power was gaining unprecedented attention in the media. In particular, critics of nuclear power expressed concern about the effects of low-levels of radioactive emissions from nuclear power plants and began to express concern that the growth of nuclear power could cause the death of thousands of Americans from cancer every year. Individuals such as Sternglass, Tamplin, and Gofman began to raise concerns about the hazards of low-level radiation and insisted that, in the absence of definitive knowledge about the consequences of exposure and the prospective growth of the nuclear

industry, permissible levels from ionizing radiation should be made more conservative (Walker 2000).

AEC responded to this growing controversy by announcing in 1971 that its proposed design objectives for nuclear power plants were incorporating into its radiation protection policies the concept of "as low as practicable" (now known as "as low as reasonably achievable" or ALARA). Implicit in the ALARA concept is the linear non-threshold dose-response relationship, which assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to an exposed individual and that the magnitude of these effects are directly proportional to dose (Kathren 1996).

In November 1972, in response to the FRC request and the growing concerns of Congress, the NAS/NRC advisory committee, now renamed the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR), published its first report, commonly referred to as BEIR I on the "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation" (NAS/NRC 1972). As described by Kathren (1996), although BEIR I did not directly address the shape of the dose response curve, it did recommend absolute risk values for various nondeterministic (i.e., carcinogenic) effects derived primarily from linear extrapolation of the data from the Japanese atomic bomb survivors with a clear implication that there was no dose threshold with respect to low dose response (NAS/NRC 1972). This highly influential committee introduced the concept of regulation of population doses such that the risk of serious injury from somatic effects would be very small relative to risks that are normally acceptable and it encouraged that guidance be established for the nuclear industry to quantify the "as low as practicable concept" and consider the net effect on the welfare of society (NAS/NRC 1972).

A NEW REGULATORY ERA (1974 TO PRESENT)

In his first energy message to Congress in 1971, President Nixon cited the concerns of the growing U.S. population's energy needs (with less than one-tenth of the world's population at the time, the U.S. consumed almost a third of the oil used worldwide) and the resulting environmental concerns arising from all sectors of energy production as factors making it necessary to create a single Cabinet-level agency responsible to coordinating all the nation's energy programs. At the time, more than sixty different agencies were making energy decisions, from the AEC to EPA and the Department of the Interior (GSG 2000). While AEC actively promoted the use of nuclear power, it found that the sudden growth of the industry created complex regulatory problems and spurred increasing public opposition (Walker 1992). Nixon argued that AEC had outlived its original mission, and that the contradictory functions of both promoting and regulating nuclear power should be split between two independent agencies. Atomic energy no longer seemed to be a complete answer to either the nation's military defense or civilian energy needs. As a result, the AEC was abolished by the Energy Reorganization Act of 1974, and two new agencies were created: the Energy Research and Development Administration (ERDA) and the Nuclear Regulatory Commission (NRC) (ERA 1974).

In addition, the influential joint House and Senate Congressional Committee on Atomic Energy, which was directly involved with practically all Federal matters in the United States relating to ionizing radiation, began to focus on atomic energy operations and protection of the growth of the nuclear industry. As discussed by Taylor (1980a, 1980b), these goals eventually aroused the ire of environmentalists, anti-nuclear activists, and certain key figures in the Administration. Public and media attention began to focus on the Committee's oversight of the AEC (and later ERDA and NRC). Shortly thereafter, with the significant changes of the roles and jurisdiction of the NRC, EPA, and ERDA, the Congressional Joint Committee on Atomic Energy was also abolished in 1977 (P.L. 95–110).

When President Jimmy Carter took office in 1977, the U.S. was already confronted with a difficult situation between the nation's long-term energy security needs and an ever-increasing demand for oil. After a bitterly cold winter in 1976–1977, this concern served to underscore the nation's dilemma (GSG 2000). In response to this energy crisis, President Carter promoted a national energy plan that focused on his belief that creating a new single cabinet level agency to unify and enforce Federal energy policy was the key to the nation's economic and national security. Although all of the President's proposals for energy solutions were not approved, his proposal for a new cabinet-level department was passed by Congress, and the Department of Energy Organization Act became law on 4 August 1977, creating the Department of Energy (U.S. DOE 1977).

During the midst of the U.S. reorganization and restructuring of its Federal agencies for radiological protection, the ICRP undertook a review of its previous recommendations and adopted a new risk-based system of radiation protection based on three principles: (1) justification of practices; (2) optimization of doses; and (3) limitations of risk. This was published as ICRP Publication 26, and today provides the foundation and basis for all current Federal and State regulations (U.S. DOE 1988; U.S. EPA 1987; U.S. NRC 1991a, 1991b), with the exception of the Department of Labor's (DOL)

Occupational Health and Safety Administration (OSHA), which still relies on ICRP 2 (1959b) as the primary foundation for its occupational health and safety regulations (OSHA 1974, 2004). In its review, the ICRP reaffirmed the justification of maintaining an annual dose equivalent to the whole body for workers of 50 mSv (5 rem) that had been introduced in 1956 (ICRP 1977, 1979). It noted that in retaining its recommended limit, the use of ALARA principles to reduce exposures in the workplace had resulted in annual average doses, in large occupational groups, of about 5 mSv (500 mrem) to workers, which was an order of magnitude less than the limit. ICRP also defined a new term called the "effective dose equivalent," which was the first time that doses from both internal and external exposures would be combined on a common risk basis. Carcinogenesis was also defined as a stochastic effect, and represented a departure from the ICRP concept of a threshold effect, previously defined as the tolerance dose. Only in cases where experimental data could prove a threshold (such as lens of the eye opacities and skin erythema) was the term "threshold" clearly applied. In addition, ICRP 26 adopted the infamous "linear hypothesis," which to this day continues to cause consternation within the health physics and radiation protection profession regarding demonstrable health effects at very low radiation doses [$\leq$ 100 mSv (10 rem) per year].

ICRP also recommended the use of quantitative risk factors, which had been developed for use in radiation protection on the basis of data from the Japanese atomic bomb survivors. These risk factors were used to derive recommended dose limits from an assumed limit on annual risk (Kocher 1991; Kennedy and Coney 1988). As a result, the ICRP assumed that the risk to radiation workers would be acceptable if the average annual mortality risk did not exceed 10^{-4}. In its recommendations, the ICRP no longer assumed that genetic risk should be the principal concern in setting dose limits for workers, and, in particular, the risk of genetic effects was assumed to be 25% of the total stochastic risk, based primarily on BEIR V studies (NAS/NRC 1980).

In 1975, when NCRP reviewed its previous recommendations, it also took the position that no changes in its recommendations were needed since its Report No. 39 was issued in 1971 (NCRP 1971, 1975). It wasn't until more than a decade later, in 1987, when NCRP issued Report No. 91, when updated recommendations for radiation protection limits were published. While the majority of its recommendations were in accord with the ICRP's 1977 revisions, NCRP proposed several recommendations that were not proposed by ICRP 26. Most notably these were: (1) a general guideline that the cumulative effective dose equivalent to a worker should not exceed 1 times the worker's age in years (i.e., $1 \times N$ instead of the former $5(N-18)$ formula); (2) use of the committed effective dose equivalent for planning purposes and use of the annual (rather than the committed) doses for post-(internal) exposure control; (3) a monthly dose limit as well as a limit on the total gestation dose to the embryo/fetus; and (4) a Negligible Individual Risk Level of 0.01 mSv (1 millirem) per year (NCRP 1987).

Another growing concern emerged in the 1970's as a result of defense-related uranium mill and mining legacy production activities in the U.S. Historically, uranium mill tailings, which are the waste byproduct of the extraction of uranium from ore (commonly referred to as yellowcake production), were not considered to be hazardous, so they remained loosely regulated by any Federal agency. This powdery material was typically stored in surface piles in the Western U.S. amounting to thousands of tons of waste, covering, in some cases, hundreds of acres of land. The tailings began to be moved from storage piles and used in construction and soil conditioning. Years later, however, communities where housing developers had used uranium mill tailings for fill materials found elevated levels of indoor radon gas and gamma radiation. Indeed, radiological and chemical assessments of the tailings found them to be highly contaminated with radionuclides, primarily ^{226}Ra, and heavy metals such as arsenic, molybdenum, and selenium (U.S. EPA 1971, 2000). The associated long-term health risks to families living in these homes were high enough to warrant cleanup actions and spurred Congress into action. In 1978, the Uranium Mill Tailings Radiation Control Act (UMTRCA) was passed, which directed EPA to set generally applicable health and environmental standards to govern the stabilization, restoration, disposal and control of effluents at both active and inactive mill tailings sites. Initially, EPA developed standards for the regulation of uranium and thorium mill tailings at 40 CFR Part 192 (U.S.EPA 1983), but later developed additional standards for the regulation of mill tailings to meet the Clean Air Act Amendments in 1979. Not only was the U.S. concerned with potential health effects for occupationally exposed workers, but in light of the chemical and radiological health consequences resulting from uranium mill tailings, environmental concerns began to arise as well.

Due to the many issues regarding radiation health effects, the NAS/NRC BEIR III Committee undertook one of the most comprehensive reviews of the available scientific literature in 1980. BEIR III's mandate, as signed by contractual agreement between the EPA and the NAS/NRC, was, in part, to determine: (1) the extent to which animal data, particularly from inbred strains, would be pertinent to estimating somatic radiation effects

in human populations; (2) the effects of dose rate and protraction on the incidence of radiation effects from high- and low-LET radiations for somatic and genetic effects; (3) the probable extent of synergistic interactions between ionizing radiation and other environmental and occupational promoters of carcinogenesis; and (4) the numerical estimates of the somatic and genetic risks to humans from low dose rate ionizing radiations.

When BEIR III released its report in 1980, it cautioned in its introductory page that, "the risk estimates presented here should in no way be interpreted as precise numerical expectation. They are based on incomplete data and involve a large degree of uncertainty, especially in the low-dose region." Nevertheless, despite dissenting views amongst two of its Committee members, BEIR III concluded that the use of the linear model at low doses probably leads to overestimates of the risk of most cancers at low doses, but that it could also be used to define the upper limits of risk. This Committee recognized that policy decisions could not be reached, nor regulatory authority exercised, without someone taking a position on the probable cancer risk associated with low-level radiation exposures. Therefore, in publishing their study, they presented the regulatory bodies with "a range of uncertainty" associated with these low-level radiation exposures within an envelope of risk estimates.

As a result of all of these studies, three Federal agencies, EPA, DOE, and NRC (including the Agreement States[‡]) were in the process of reviewing these new international and national radiation protection recommendations for possible incorporation into existing regulations or guidance. NRC was the first of the agencies to issue an advanced notice of proposed rulemaking in 1980, which requested comments on what possible topics should be considered for revision in 10 CFR Part 20 (U.S. NRC 1980). Once comments from various stakeholders had been received, NRC staff began to formulate the proposed rule that was issued for public comment in 1986 (U.S. NRC 1986). At the same time, EPA had been conducting several public meetings in connection with its revised Presidential Federal Guidance on Occupational Exposure. Due to the amount of time to incorporate over 800 sets of public comments on the proposed rule, and the timing of the issuance of NCRP's Report No. 91 in 1987, and later, ICRP Publication 60 in 1991, the final revision to 10 CFR Part 20 did not incorporate the proposals for the ICRP reduced dose limit, the NCRP proposed lifetime limit for workers, or the concept of a negligible individual risk (U.S. NRC 1991a, 1991b). In 1991, when NRC's rule was finalized, it did incorporate the final EPA Presidential Federal Guidance on Occupational Exposure that had been issued by EPA in 1987 and the ICRP 26 recommendations for annual total effective dose equivalent to the whole body for workers of 50 mSv (5 rem). As summarized in NRC's Statement of Considerations, secondary limits were expressed as annual limits on intakes (ALIs) and for inhalation, were called derived air concentration (DACs) for radionuclides (U.S. NRC 1991a, 1991b). These secondary limits were based on either an annual effective dose equivalent of 50 mSv (5 rem), for stochastic risk, or on an annual limit on annual dose equivalent to any organ or tissue of 0.5 Sv (50 rem), for preventing nonstochastic effects, whichever was more restrictive. For further discussion of these and other development of radiation standards, Kocher (1991) provides an excellent discussion of the radiation protection standards and delineation of environmental radiation standards.

As mentioned briefly above, the ICRP, in 1990, issued a press release indicating that it would issue revised recommendations based upon newer studies of radiation risks, such as the 1988 report of the United Nations Scientific Committee on the Effects of Atomic Radiation and the 1988 and 1990 reports of the NAS/NRC Biological Effects of Ionizing Radiation, commonly referred to as BEIR IV and BEIR V, respectively (UNSCEAR 1988; NAS/NRC 1988, 1990; U.S. NRC 1991a, 1991b). ICRP's press release indicated that it would allow for year-to-year flexibility as long as the total dose to workers remained below 100 mSv (10 rem) in 5 consecutive years and no one single year exceeded 50 mSv (5 rem) (U.S. NRC 1991a, 1991b). ICRP's reduction in its previous dose limit was based primarily on an assumed increase in risk of stochastic effects per unit dose by a factor of about three, as derived from Japanese atomic bomb survivors (NAS/NRC 1990; Kocher 1991). Due to the routine practice of maintaining radiation exposures ALARA, however, the NRC did not believe that additional reductions in the dose limits would be urgently required, and supported this statement by citing that about 97% of the occupational workers at the time received annual doses less than 20 mSv (2 rem), which was consistent with proposals made by the ICRP. The NRC did, however, state that it would carefully review the ICRP recommendations once they became final, and determine, at a later time, if additional reductions were deemed to be necessary.

At the same time it was finalizing its revised regulations for radiation protection, NRC was also involved in what turned out to be a highly contentious and controversial issue that reached all areas of the media, public, and the Congress. During the development of its

[‡] An Agreement State is a State that has signed an agreement with the NRC to regulate the use of byproduct and small quantities of special nuclear material and source material. As of October 2004, there are 33 Agreement States in the United States.

revisions to 10 CFR Part 20, NRC (and its predecessor, the AEC) had determined that they had granted thirty-nine exemptions for the use of low-level radioactive materials that they concluded posed negligible public health risks (Walker 2000). These exemptions included using very low levels of radioactive material in such items as clocks, watches, and compasses for nighttime illumination, as well as commercial uses in glassware and smoke detectors. In a separate regulatory action from the 10 CFR Part 20 rulemaking, in 1990, NRC proposed a Below Regulatory Concern (BRC) policy statement to define a level at which it deemed was below regulatory control. NRC was not alone in its philosophy, since the Low-Level Radioactive Waste Policy Amendments Act of 1985 actually instructed the NRC to determine which waste streams: (1) posed enough of a public risk to be sent to specially-constructed landfills; and (2) posed so little risk that they could be disposed of in an ordinary landfill (LLWPA 1985). Although scientists and regulators understood the differences between a BRC level, which represented levels that were low enough to not require regulatory control, but still posed a slight risk to exposed individuals, vs. that of a *de minimus* level, which represented a threshold below which risk of radiation injury was absent, this distinction was lost on the public. Issuance of the BRC Policy resulted in intense, widespread public concern, including legislation at the national, State, and local levels that would prevent the BRC policy from taking effect. Although the NRC and its staff tried to resolve conflicting views and eventually pursued a consensus-building process in 1991, the mistrust and concern it had generated with the public and Congress was too great to overcome (Jones 2004). In the Energy Policy Act of 1992, Congress formally revoked the BRC Policy Statement and later, in June 1993, NRC officially withdrew the policy (Walker 2000).

About the same time as NRC, in 1991, DOE proposed regulations to codify requirements for occupational workers that were previously contained in DOE Directives (U.S. DOE 1991). Although DOE had the benefit of considering the ICRP 60 and NCRP proposals for both a reduction in occupational dose and a lifetime limit in its proposed regulations in 1991, the final regulations, after a substantial public comment period, did not endorse either one. As DOE explained in its 1993 Statement of Considerations for its final rule at 10 CFR Part 835, because the Presidential Federal guidance had not yet incorporated the ICRP 60 recommendations, and that because its annual doses were already very low, it would not appreciably reduce the collective doses overall (U.S. DOE 1993a, 1993b). Amongst DOE workers, annual doses were in general below the proposed limit of 20 mSv (2 rem) per year. Consequently, establishing a lifetime limit would not provide sufficient reduction in either the average or collective dose to DOE workers (U.S. DOE 1993a). DOE further stated that a worker's future employment could be jeopardized if an individual received high exposures early in their career (U.S. DOE 1993a). DOE's final rule (10 CFR Part 835), which became effective 13 January 1993, also implemented the Presidential Radiation Protection Guidance to Federal Agencies for Occupational Exposure and other recommendations proposed by the ICRP and NCRP (U.S. DOE 1991). 10 CFR Part 835 established regulations to ensure that DOE facilities are operated in a manner such that occupational radiation exposure to workers is maintained within acceptable limits and as far below these limits as is reasonably achievable using the principles of ALARA.

Under DOE, NRC, and Agreement States final rules, the internal component of the occupational exposure limit continues to be based on the concept of a 50-y committed dose instead of an annual committed dose. This 50-y committed dose provided additional benefits to agencies that adopted them, such as enhanced protection to workers, consistency with the national and international scientific committees (e.g., NCRP, ICRP, UNSCEAR), simplification of record keeping associated with internal dose, simplification of transfer of workers between DOE, NRC, and Agreement State regulated facilities, and consistency between the limits for occupational exposure and the limits used by Federal and State agencies for the protection of members of the public. In addition, all of these revised regulations increased the emphasis on ALARA programs. Even in today's regulatory arena, emphasis on ALARA program implementation continues to be an extremely effective tool in maintaining doses for occupational workers well below the current limits and those recommended by the ICRP. In fact, in 2003, the annual average occupational exposures for DOE personnel was 0.83 mSv (83 millirem), while for personnel at NRC licensed facilities, it was 2.3 mSv (230 millirem).[§]

As Federal and State regulations were being proposed and implemented, EPA continued in its role as a standards-setting body and issued many technical documents. Since its establishment, EPA (or its predecessor the FRC) has issued four Presidential Federal Guidance documents, five Federal Guidance reports, and several Protective Action Guides for Federal and State agency use (Table 1). Presidential Federal Guidance is unique in that it provides the principles and basic standards for Federal and State radiation protection programs that are developed in cooperation with other Federal agencies

[§] Karagiannis H. Personal correspondence to C. Jones on DOE and NRC average occupational radiation exposures for CY 2003; August 17, 2004.

Table 1. Selection of relevant radiation protection guidance and regulations from 1957 to present.

Year	Federal Agency	Document
1957	Atomic Energy Commission (AEC)	Basic Standards for Radiation Protection (10 CFR Part 20)
1960	Federal Radiation Council (FRC)	Presidental Federal Guidance on Occupational and Population Radiation Exposures
1961	FRC	Federal Guidance on Limiting Certain Internal Radiation Exposures
1964	FRC	Federal Protective Action Guides for I-131
1965	FRC	Federal Protective Action Guides for Sr-89, Sr-90, and Cs-137
1967	FRC	Presidential Guidance for the Control of Radiation Hazards in Uranium Mining
1969	FRC	Federal Guidance on Radon Exposures in Uranium Mines
1971	Occupational Health & Safety Administration (OSHA)	OSHA Ionizing Radiation Protection Standards (29 CFR Part 1910.96) (U.S. Department of Labor 1970)
1973	Food & Drug Administration (FDA)	Performance Standards for Ionizing Radiation Emitting Products (21 CFR Part 1020)
1976	U.S. Environmental Protection Agency (U.S. EPA)	U.S. EPA Interim Drinking Water Standards for Radionuclides (40 CFR Part 141)
1976	U.S. EPA	Radiation Protection Guidance for Diagnostic X-Rays (Federal Guidance Report No. 9)
1977	U.S. EPA	Environmental Protection Standards for Nuclear Power Operations (40 CFR Part 190)
1978	U.S. EPA	Presidential Federal Guidance on Diagnostic X-Ray Exposures
1981	U.S. Nuclear Regulatory Commission (U.S. NRC)	Requirements for Disposal of High-Level Radioactive Waste in Geologic Repositories (10 CFR Part 60)
1982	U.S. NRC	Requirements for Land Disposal of Low-Level Radioactive Waste (10 CFR Part 61)
1982	U.S. EPA	Advisory for Protective Action Guides for Radioactive Contamination in Food
1984	U.S. EPA	The Radioactivity Concentration Guides (Federal Guidance Report No. 10)
1985	U.S. EPA	Air Emission Standards for Radionuclides (40 CFR Part 61)
1991	U.S. NRC	Basic Standards for Protection Against Radiation—Final Rule (10 CFR Part 20)
1987	U.S. EPA	Presidential Federal Guidance on Limiting Occupational Radiation Exposures
1988	U.S. EPA	Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion (Federal Guidance Report No. 11)
1989	U.S. EPA	National Emission Standards for Hazardous Air Pollutants (40 CFR Part 61)
1991	U.S. EPA	Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (U.S. EPA-400-R-92-001)
1993	U.S. Department of Energy (U.S. DOE)	Occupational Radiation Protection—Final Rule (10 CFR Part 835)
1993	U.S. EPA	External Exposure to Radionuclides in Air, Water, and Soil (Federal Guidance Report No. 12)
1999	U.S. EPA	Cancer Risk Coefficients for Environmental Exposure to Radionuclides (Federal Guidance Report No. 13)
2001	U.S. EPA	Public Health and Environmental Radiation Standard for Yucca Mt., NV (Energy Policy Act of 1992)
2001	U.S. NRC	Disposal of High-Level Waste in Geologic Repositories (10 CFR Part 60)

and that rise to the level requiring Presidential approval. Of the two Presidential guidance documents that replaced guidance developed by the FRC for occupational workers, one provided guidance for medical uses of radiation, and the last one, issued in 1987, provided Federal Guidance on occupational radiation exposures. In 1994, EPA proposed revised guidance for the public; however, additional changes have been made since that time, and EPA is awaiting final action on its most recent proposals. Other EPA-issued technical documents that have proven to be invaluable to health physicists include Federal Guidance Report (FGR) 11, "Limiting values of radionuclide intake and air concentration and dose conversion factors for inhalation, submersion, and ingestion," and FGR 12, "External exposure to radionuclides in air, water, and soil," which provide current scientific and technical information for radiation dose and risk assessment to support the implementation of Federal and State regulatory programs (U.S. EPA 1988, 1993). Although this guidance may be revised in the future, any future reductions in the dose limits by any Federal agency would be subject to future public rulemaking proceedings.

ICRP and NCRP have advanced in proposing further radiation protection recommendations in ICRP 60 and NRCP Report No. 116 that have yet to be fully implemented in the United States (ICRP 1991; NCRP 1993). Both organizations, as well as many other agencies nationally, continue to review the large body of information concerning the effects of ionizing radiation on people and animals to evaluate the need for future changes concerning recommendations for limiting exposures to radiation. Table 2 presents a chronology of national and international radiation protection standards and recommendations since 1947.

The next set of fundamental ICRP recommendations, intended to replace the 1990 recommendations from ICRP Publication 60, have recently been developed and are undergoing, for the first time, a public consultation review process on its internet site, www.icrp.org (ICRP 2004). Although it still embraces the concepts of optimization, justification, and limitations on dose, ICRP

Table 2. *Chronology* of radiation standards: occupational external whole-body dose equivalents.[a]

Year	National Council on Radiation Protection and Measurements (NCRP)[b]		International Commission on Radiological Protection (ICRP)		Federal Radiation Council (FRC)[c] U.S. Environmental Protection Agency (U.S. EPA)[d]		Atomic Energy Commission (AEC)[e] Energy Research and Development Administration (ERDA)[f]		Nuclear Regulatory Commission (U.S. NRC)[g] U.S. Department of Energy (U.S. DOE)[h] Occupational Health and Safety Administration (OSHA)[i]	
	Criteria	Reference	Criteria	Reference	Criteria	Reference	Criteria	Reference	Criteria	Reference
1947	0.1 rad d^{-1} 0.5 rad wk^{-1}	NBS 1934 (Handbook 18)	0.2 rad d^{-1} 1.0 rad wk^{-1}		FRC established in 1960		0.1 rad d^{-1}	NBS 1934 (Handbook 18)	Energy Reorganization Act of 1974 created the U.S. Nuclear Regulatory Commission and the Energy Research and Development Organization	
1949	0.3 rad wk^{-1}	NBS 1949 (Handbook 42)	0.2 rad d^{-1} 1.0 rad wk^{-1}				0.1 rad d^{-1}		The U.S. Department of Energy was formed in 1977 under the U.S. Department of Energy Organization Act	
1950			0.3 rad wk^{-1} bone 0.3 rad wk^{-1} skin	NBS 1950 (Handbook 47)			0.3 rad wk^{-1} 3.9 rad/13 wk	NBS 1950 (Handbook 47)		
1951							3 rad $series^{-1}$ 2 rad $series^{-1}$ 3.9 rad/13 wk	LASL 1952		
1952							3.9 rad/13 wk			
1954	3 rad/13 wk 0.3 rad wk^{-1} max 15 rem y^{-1}	NBS 1954 (Handbook 59)					3 rad/13 wk 0.3 rad wk^{-1} max 15 rem y^{-1}	NBS 1954 (Handbook 59)		
1957	5 rem y^{-1} avg 12 rem y^{-1} max	NBS 1954 (Handbook 59)					3 rad/13 wk 0.3 rad wk^{-1} max 15 rem y^{-1}	NBS 1954 (Handbook 59)		
1958	0.3 rem wk^{-1} max 3 rem/13 wk 12 rem y^{-1} max 5(N-18) rem[j]		0.1 rem wk^{-1} 3 rem/13 wk 5(N-18) rem	ICRP 1959 (Report 1)			0.3 rem wk^{-1} 3 rem/13 wk 12 rem y^{-1} 5(N-18) rem			
1959			0.1 rem wk^{-1} 3 rem/13 wk 5(N-18) rem							
1960			0.1 rem wk^{-1} 3 rem/13 wk 5(N-18) rem		3 rem wk^{-1} max 3 rem/13 wk 12 rem y^{-1} max 5(N-18) rem	FRC 1960 (Report 1)	3 rem/13 wk 5 rem y^{-1} avg 5(N-18) rem	FRC 1960 (Report 1)		
1965			3 rem/13 wk 5 rem y^{-1} max	ICRP 1966 (Report 9)	"					
1970					The President's Reorganization Act Plan No. 3 of 1970 abolished FRC and transferred its function to the Administrator of U.S. EPA					
1971	3 rem/13 wk 5 rem y^{-1}	NCRP 1971 (Report 39)							3 rem/13 wk 5 rem y^{-1} avg 5(N-18) rem	29 CFR 1910.96 (OSHA 1971)
1974	3 rad/13 wk 5 rem y^{-1}				3 rem wk^{-1} max 3 rem/13 wk 12 rem y^{-1} max 5(N-18) rem		NCRP 1971 (Report 39) AEC abolished in 1974		3 rem/13 wk 5 rem y^{-1}	10 CFR Part 20 & U.S. DOE Order 5480.11 (U.S. DOE 1994)
1977			5 rem y^{-1} acceptable risk	ICRP 1977 (Report 26)						29 CFR 1910.1096 (OSHA 1974)
1987	50 mSv y^{-1} & 10 mSv × age (y) cumulative effective dose;[k] 150 mSv y^{-1}—Lens of eye; & 500 mSv y^{-1} —Other organ, tissue, or extremities[l] 5 mSv and 0.5 mSv to Embryo/Fetus once pregnancy is known[m]	NCRP 1987 (Report 91)			5 rem y^{-1} 15 rem y^{-1}—Eye 50 rem $^{-1}$—Other organ or tissue 50 rem y^{-1}—Extremities ALIs & DACs[n]	Presidential Federal Guidance (U.S. EPA 1987)				

Table 2. *Continued*

Year	National Council on Radiation Protection and Measurements (NCRP)[b]		International Commission on Radiological Protection (ICRP)		Federal Radiation Council (FRC)[c] U.S. Environmental Protection Agency (U.S. EPA)[d]		Atomic Energy Commission (AEC)[e] Energy Research and Development Administration (ERDA)[f]		Nuclear Regulatory Commission (U.S. NRC)[g] U.S. Department of Energy (U.S. DOE)[h] Occupational Health and Safety Administration (OSHA)[i]	
	Criteria	Reference	Criteria	Reference	Criteria	Reference	Criteria	Reference	Criteria	Reference
1990			20 mSv y^{-1}, avg over 5 y (100 mSv in 5 y) and 50 mSv in any single year; 150 mSv y^{-1}—Lens of eye; 500 mSv y^{-1} Other organ tissue, or extremities; 2 mSv woman's abdomen; ALIs						Annual limits for adults: 5 rem y^{-1} 15 rem y^{-1}—Lens of eye 50 rem y^{-1}—Other organ or tissue 50 rem y^{-1}—Extremities ALIs & DAC Minors: 0.1 times annual limits for adults 0.5 rem over gestation period for Embryo/Fetus	10 CFR Part 20 (U.S. NRC 1991a) Effective 1991 with deferred implementation by U.S. NRC licenses until 1993
1993	50 mSv y^{-1} and 10 mSv × age (y) 150 mSv y^{-1}—Lens of eye 500 mSv y^{-1}—Other organ, tissue, or extremities; 0.5 mSv to Embryo/Fetus once pregnancy is declared[g] ARLIs[o]	NCRP 1993 (Report 116)							Annual limits for adults: 5 rem y^{-1} 15 rem y^{-1}—Lens of eye 50 rem y^{-1}—Other organ or tissue 50 rem y^{-1}—Extremities ALIs & DAC 0.5 rem over gestation period for Embryo/Fetus	10 CFR 835 (U.S. DOE 1993) Effective Jan 1993
1994										10 CFR 20 (U.S. NRC 1991a) Effective for all Agreement States in 1994

[a] Adapted from U.S. DOE 1997.
[b] From 1929–1946: Advisory Committee on X-Ray and Radium Protection; from 1946–1956: National Committee on Radiation Protection (NCRP); From 1956–1964: National Committee on Radiation Protection and Measurements; From 1964–Present: National Council on Radiation Protection and Measurements.
[c] FRC was established by E.O. 10831 and P.L. 86-373.
[d] U.S. EPA was established by Reorganization Plan No. 3 of 1970.
[e] AEC was established by the Atomic Energy Act of 1946 under the McMahon Bill.
[f] ERDA was established under the Energy Reorganization Act of 1974.
[g] U.S. NRC was established under the Energy Reorganization Act of 1974.
[h] U.S. DOE was established under the U.S. Department of Energy Act of 1977.
[i] OSHA was established under the Occupational Safety and Health Act of 1970.
[j] N-18 is the number of years of occupational radiation exposure after age 18, where N is the worker's age in years—a guideline used to show maximum cumulative occupational radiation dose to an adult worker. This approach is no longer used in either the U.S. DOE or U.S. NRC occupational exposure regulations.
[k] The concepts of equivalent dose and dose equivalent changed (NCRP 1987).
[l] "Extremity" is defined as the forearms and hands, or the lower legs and feet.
[m] The occupational limit for "declared pregnancy women," as defined in 10 CFR 20.1208, cannot exceed 0.5 rem (5 mSv) during the gestation period (U.S. NRC 1991a).
[n] The use of ALIs (Annual Limit on Intake) and DACs (Derived Air Concentrations) from ICRP 26 and 30 were also adopted in this Guidance.
[o] Annual Reference Levels of Intake (NCRP 1993).

proposes individual maximum dose constraints for workers and members of the public. ICRP's 2005 recommendations will attempt to provide a more simplified, generally applicable system of protection that it hopes will better clarify its objectives and provide a sound basis for a more formal system needed by operating management and regulators. ICRP anticipates that these recommendations will be finalized in 2006 after a through review, incorporation of public comments, and resolution of technical issues.

CONCLUSION

This general historical review of *Health Physics* articles covering the U.S. radiation protection regulations, recommendations, and standards for radiation protection of occupational workers and the public only captures a fraction of the many issues that have developed in this area over the past 50 years. It is intended to serve as a useful reference and compendium of the major radiation protection standards and guidance that have helped to shape our nations' radiation protection programs. As described by Mills (1985), public health and regulatory agencies typically consider three principal elements as their responsibility in protecting individuals against the adverse effects of ionizing radiation: health, benefit, and cost. Over the past 50 years, the radiation protection standards for both workers and the public have changed remarkably little over time. As Kocher (1991) notes, the dose limit from whole-body exposure for workers has been reduced by only about an order of magnitude since standards for external exposure were first developed in 1947. The Federal agencies described in this article continue to use these three guiding principles, in addition to the evaluation of acceptable risk in re-evaluating, assessing, and developing proposed changes to regulations and guidance. As a result, limits are derived explicitly by quantifying risk, and by judging the acceptability of risk through a comparison of risks experienced by workers in industries not involving radiation exposures. By some measures, the "acceptable" risk of mortality is 10^{-4} per year for workers, and 10^{-6} to 10^{-5} per year for members of the public, based on an estimate of radiation-induced fatal cancers and serious, hereditary disorders. The upper limits are set to avoid non-stochastic (threshold) effects, such as cataracts. Together, the recommendations by international and national bodies such as the ICRP, NCRP, UNSCEAR, NAS/NRC, and the Health Physics Society Accredited Standards Committees have led to the radiation philosophy that is used by the majority of Federal and State agencies today.

As mentioned earlier, the Presidential Federal Guidance and the vast majority of the current regulatory framework for both members of the public and those occupationally exposed reflect developments in the principles that underlie radiation protection and advances in related sciences that have occurred since the original promulgation of standards by the AEC in 1957. These documents, which remain currently in effect by the Presidential Federal Guidance for Occupational Exposure, as well as NRC, DOE, and Agreement States regulations, put into practice the recommendations of ICRP 26.

One common theme amongst all the organizations and regulatory entities and recommending bodies is the philosophy that radiation protection be based on the principals of justification, dose limitation and the application of ALARA, economic and social factors being taken into account (NCRP 1993, 1998). NCRP has defined ALARA as "simply the continuation of good radiation-protection practices which traditionally have been effective in keeping the average individual exposures for monitored workers well below the limits" (NCRP 1993). It clearly does work both in practice and in theory.

There is no question that legal, legislative, and regulatory actions in relation to radiation protection present a formidable double-edged sword (Taylor 1980a, 1980b). Indeed, the transition from a change in the basic radiation protection recommendations proposed by national and international scientific bodies to proper interpretation and effective implementation by the regulator is sometimes a tortuous path filled with differences of opinion among stakeholders, licensees, and scientific authorities (Vallario 1988). The process by which radiation protection recommendations, regulations, and standards develop is a helpful aid in striving to achieve uniformity in the overall U.S. radiation protection system and which should be used to apply a sound scientific basis for action (enforcement or otherwise), should the need arise. National policy establishes a regulatory regime, under which society can realize the beneficial uses of radiation while at the same time protecting workers, the public and the environment from the potential hazards of radiation. It is through our continuing open, inclusive, and democratic processes where we as a society must strike the balance that defines adequate radiation protection policy, builds public trust, and allows the radiation professionals to properly implement and manage that policy (Jones 2004). It is important to continue to strive in achieving a balance between the risks associated with exposure to ionizing radiation and the societal benefits that this science has brought us. Let our history and experience of many agencies in the

standards and regulatory development processes continue to illustrate our ability to work together in ensuring the future health and safety of all humankind.

Note—The views expressed in this journal article are not necessarily those of the U.S. Nuclear Regulatory Commission.

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