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The Nuclear Regulatory Commission's Regulation of Radiation Hazards in the Workplace: Present Problems and New Approaches to Reproductive Health*

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INTRODUCTION

On December 20, 1985, the Nuclear Regulatory Commission (NRC) proposed revisions to its Standards for Protection Against Radiation [hereinafter Standards].¹ If adopted, the new Standards will provide additional protection for millions of workers and their unborn children. The effects of the Standards will extend, however, far beyond the health of those exposed to radiation. Specifically, the NRC's proposal may provide a new paradigm for regulating health hazards that have no safe threshold level of exposure. It will also focus debate on whether or not women should be precluded from working in fetotoxic environments.

The contemporary wisdom underlying the NRC's current Standards is that a safe threshold level of exposure to radiation exists.² The threshold theory posits that workers may be exposed repeatedly to toxicants under certain levels without adverse effect.³

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* This article is based on a contractor's report to the Office of Technology Assessment (OTA), U.S. Congress, by Michael Baram and Neal Smith, entitled *Reproductive Hazards in the Workplace: Nuclear Regulatory Commission Regulation* (Nov. 1, 1984), portions of which were included in OTA's report to Congress, OFFICE OF TECHNOLOGY ASSESSMENT, 99TH CONG., 1ST SESS., *REPRODUCTIVE HEALTH HAZARDS IN THE WORKPLACE* (1985).

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1. 50 Fed. Reg. 51,992 (1985), *reissued with corrections*, 51 Fed. Reg. 1091 (1986). The current Standards are codified at 10 C.F.R. pt. 20 (1986). Also see the NRC's assessment of the proposed Standards at 51 Fed. Reg. 30,870 (1986).

2. 50 Fed. Reg. at 51,992.

3. For example, the American Conference of Governmental Industrial Hygienists sets nonbinding standards known as Threshold Limit Values (TLV's). By definition, TLV's are

The fundamental recognition driving the NRC's new proposal is that no threshold exists under which exposure to radiation is safe.⁴ Because no safe threshold exists, the NRC proposes setting radiation standards by quantifying the risk associated with various exposure levels and then determining the magnitude of risk deemed acceptable.⁵ Under this approach, the NRC's exposure limits would be supported by a scientifically accurate, health-based rationale.

The novelty of the NRC's proposed method of establishing exposure limits alone warrants a close examination of the recommendations. There is, however, another reason to look at the NRC's proposal: Many occupational toxicants may not have a safe threshold level of exposure. Should continuing research further erode the threshold hypothesis, the NRC's proposed acceptable-risk approach may prove to be the paradigm method for other agencies of establishing occupational exposure standards for both radioactive and nonradioactive toxicants.

The adoption of an acceptable-risk rationale for its Standards has led the NRC to reassess the current health risk from *in utero*⁶ exposure of the embryo/fetus and to recommend different exposure limits for pregnant workers than those applicable to other workers.⁷ This proposal is in direct conflict with the equal employment opportunity ideal of Title VII of the Civil Rights Act of 1964⁸ and the prohibition on disparate treatment of pregnant workers embodied in the Pregnancy Discrimination Act.⁹ The importance of this conflict with Title VII is magnified by the theoretical alliance between the NRC's proposal and the many corporate programs¹⁰ that currently seek to exclude both fertile and pregnant women from employment in fetotoxic work environments. The NRC's proposed differential treatment of only pregnant workers may unintentionally provide support for discrimination against fertile and pregnant women in the name of reproductive health. This threat to equal employment opportunities for women also calls for a close analysis of the proposed Standards.

"the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect." AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS, TLV'S: THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES IN WORKROOM AIR ADOPTED BY ACGIH FOR 1981, at 3 (1981). For additional information on the threshold theory see Stokinger, *The Case for Carcinogen TLV's Continues Strong*, OCCUPATIONAL HEALTH & SAFETY, Mar.-Apr. 1977, at 54 and J. GOFMAN, RADIATION AND HUMAN HEALTH (1981).

4. 50 Fed. Reg. at 52,000-01.

5. *Id.* at 51,992-93.

6. The phrase "*in utero*" refers to the state of being in the uterus.

7. 50 Fed. Reg. at 52,008-09.

8. 42 U.S.C. § 2000e (1982 & Supp. III 1985).

9. Pub. L. No. 95-555, 92 Stat. 2076 (1978) (amending Title VII of the Civil Rights Act of 1964).

10. See *infra* notes 372-73 and accompanying text.

This Article uses the pendency of the NRC's recent proposal as an occasion to review the problem of radiation hazards in the workplace and the regulatory framework designed to address that problem and to examine the proposed Standards and their potential implications. Ultimately, this Article supports the NRC's proposed Standards. Prior to reaching that conclusion, this Article finds that the problem of occupational radiation exposure is both serious and complex and that the overall regulatory structure established to address this problem could and should be improved. Although the equal employment concerns of women are regarded as a serious social priority, this Article concludes that the NRC's proposal, unlike corporate programs that broadly exclude fertile and pregnant women from fetotoxic environments, is justified in light of the severe health risks posed to exposed embryos and fetuses.

The Article is divided into five Sections. Section I contains a scientific summary of the physical nature of radiation, the mechanisms by which radiation causes biological injury, and the types of injuries that may result from occupational exposure. Section II traces the evolution of the NRC's predominant role in the regulation of occupational exposures to radiation and examines some of the shortcomings of the current regulatory structure. Sections III and IV present a detailed analysis and critique of both the current and proposed Standards for Protection Against Radiation. Both versions are evaluated from a general health and a reproductive health perspective. Section V addresses the conflict between the NRC's proposed differential restriction on the exposure of pregnant women and Title VII.

I

RADIATION, EXPOSURE, AND REPRODUCTIVE RISK

For many years, the scientific community has recognized the correlation between human exposure to ionizing radiation¹¹ and adverse bio-

11. Radiation is a generic term that describes the emission and propagation of energy through space. In its broadest usage, radiation includes acoustic, electromagnetic, and particulate energy propagation.

Ionization is the process that results in the formation of ions, i.e., atoms or molecules that carry an electrical charge by virtue of having gained or lost one or more electrons.

The term "ionizing radiation" encompasses those types of radiation that can transfer sufficient energy to cause ionization in an irradiated material. When the material is living tissue, ionization can result in chromosomal aberrations that have a drastic effect on the irradiated individual as well as on his or her offspring and descendants. In considering reproductive hazards, only ionizing radiation is relevant.

Acoustic radiation has never been observed to possess sufficient energy to cause ionization. Electromagnetic radiation is best visualized as a wave and is classified according to frequency: radiofrequency, microwave, infrared, visible, ultraviolet, X-ray, and gamma ray. High-frequency electromagnetic radiation, e.g., X-rays and gamma rays, possesses sufficient energy to cause ionization. Particle radiation, so named because its nature is best described by the theory of particle dynamics, includes alpha, beta, and neutron radiation and is known to cause ionization.

logical changes. The first report of human injury came just months after Roentgen's 1895 paper announcing the discovery of X-rays.¹² The first case of X-ray induced cancer was reported in 1902.¹³ In 1927, Muller, whom scientists credit with the discovery of radiation-induced mutation, first published his research results in this area.¹⁴

Early evidence of the hazards of radiation exposure in the workplace came from observation of occupational groups that were subject to chronic exposure: radiologists, dentists, miners exposed to radioactive air, and radium industry employees.¹⁵ A classic study of occupational exposure focused on radium-dial painters.¹⁶ Early in this century, the luminous material on watches was painted by hand, commonly by young women. The workers used their lips and tongues to moisten their brushes to keep them sharp. The paint, however, contained radium, and follow-up studies of the workers who had ingested radium showed an increased incidence of malignancies resulting from the accumulation of radium in their bones.¹⁷

There are numerous contemporary examples of occupational exposure to radiation, and their number is likely to increase with continued technological development.¹⁸ Workers in four main occupational categories experience regular on-the-job exposure to radiation: medicine, industry, government, and nuclear fuel production.¹⁹ Medicine accounts for forty-four percent of the total exposed workforce,²⁰ industry for

12. For a summary of early reports describing the biological effects of X-rays, see Glaser, *First Observations on the Physiological Effects of Roentgen Rays on the Human Skin*, 28 AM. J. PHYSICS 75 (1932).

13. The case was that of Clarence Dally, an assistant to Thomas Edison, who had worked with X-rays since 1896. Death resulted from a malignancy that spread from its origin in Dally's exposed hands. D. SERWER, *THE RISE OF RADIATION PROTECTION: SCIENCE, MEDICINE AND TECHNOLOGY IN SOCIETY, 1896-1935*, at 40 (Brookhaven National Laboratory Report No. 22,279, 1976).

14. Muller, *Artificial Transmutation of the Gene*, 66 SCIENCE 84 (1927).

15. M. BARNETT, *THE BIOLOGICAL EFFECTS OF IONIZING RADIATION: AN OVERVIEW* 1, 7-8 (U.S. Dep't of Health, Education and Welfare Publication No. 77-8004, 1976); see also J. GOFMAN, *supra* note 3 (discussing particular occupations that have long been known to entail increased health risk from radiation exposure).

16. Martland, *The Occurrence of Malignancy in Radioactive Persons: A General Review of Data Gathered in the Study of Radium Dial Painters, with Special Reference to the Occurrence of Osteogenic Sarcoma and the Interrelationship of Certain Blood Diseases*, 15 AM. J. CANCER 2435 (1931).

17. See *id.* at 2436-37.

18. See generally J. GOFMAN, *supra* note 3.

19. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, 32 U.N. GAOR Annex E at 230-54, U.N. Doc. A/32/40 (1977); U.S. ENVTL. PROTECTION AGENCY, *OCCUPATIONAL EXPOSURE TO IONIZING RADIATION IN THE UNITED STATES: A COMPREHENSIVE REVIEW FOR THE YEAR 1980 AND A SUMMARY OF TRENDS FOR THE YEARS 1960-1985* (1984).

20. U.S. ENVTL. PROTECTION AGENCY, *supra* note 19, at 40. Medical exposures are encountered by any worker involved in the diagnostic or therapeutic use of radioactive materials or of an electronic source of ionizing radiation, e.g., an X-ray machine. A roster of exposed

twenty-three percent,²¹ government for sixteen percent,²² and nuclear fuel production for eleven percent.²³ Other miscellaneous occupations account for the remaining six percent.²⁴

Despite widespread use of radiation in the workplace and extensive regulation of radioactive materials, there are no detailed demographic reports of the number of workers currently exposed. Crude estimates indicated that approximately 457,000 workers were exposed in 1960.²⁵ By 1970, the number had grown to an estimated 780,000,²⁶ an increase of eighty percent in ten years. By 1975, about 1.1 million workers were being exposed to radiation annually.²⁷ A 1984 survey indicated that approximately 1.32 million workers were exposed to radiation in 1980, and it projected an estimate of 1.64 million exposed workers in 1985.²⁸ More current figures for the number of workers annually exposed to radiation are not yet available.

Many exposed workers may be unaware of the increased health risks to which their jobs subject them.²⁹ For example, cosmic radiation in-

personnel includes physicians, nurses, orderlies, radiologists, X-ray technicians, isotope technicians, medical physicists, laboratory technicians, dentists, dental hygienists, chiropractors, and veterinarians. *Id.*

21. *Id.* The bulk of industrial occupations that entail exposure involve radiography. Other jobs include the manufacture and distribution of radiopharmaceuticals and electronic sources of radiation, as well as work involving miscellaneous uses in research and development, thickness gauging, quality control, and even timepiece dial painting. *Id.*

22. *Id.* The vast majority of radiation exposures suffered by federal employees occur under the jurisdiction of the Department of Defense (e.g., military personnel associated with nuclear-powered vessels) and the Department of Energy (e.g., contractors and their employees involved in the development of weapons and reactors). Other federal employees exposed to radiation include those conducting research with the National Institute of Health, the National Aeronautics and Space Administration, and the Public Health Service, as well as those exposed in connection with the medical activities of the military and the Veterans' Administration hospitals. *Id.*

23. *Id.* Some of the largest occupational exposures are to employees involved in the nuclear fuel cycle. The phrase "nuclear fuel cycle" denotes the cradle-to-grave sequence of uranium mining; fuel fabrication; fueling, maintenance, and operation of nuclear reactors; fuel reprocessing; and nuclear waste removal, transportation, storage, and disposal. *See id.*

24. This category includes nonuranium miners, teachers, employees of educational research laboratories, and airline flight crews. *Id.*

25. U.S. ENVTL. PROTECTION AGENCY, ESTIMATES OF IONIZING RADIATION DOSES IN THE UNITED STATES 1960-2000, at 150 (1972); *see also* U.S. ENVTL. PROTECTION AGENCY, *supra* note 19, at 54.

26. U.S. ENVTL. PROTECTION AGENCY, *supra* note 19, at 54.

27. U.S. ENVTL. PROTECTION AGENCY, OCCUPATIONAL EXPOSURE TO IONIZING RADIATION IN THE UNITED STATES: A COMPREHENSIVE SUMMARY FOR THE YEAR 1975, at 39 (1980).

28. U.S. ENVTL. PROTECTION AGENCY, *supra* note 19, at 54.

29. Arguably, a causal factor of employee ignorance of the health risk to which he or she is exposed may be the regulator's use of the term "permissible dose." *See, e.g.*, 10 C.F.R. § 20.101 (1986). Two members of the Nuclear Regulatory Commission have expressed this belief:

We have found in discussions with people both in the power industry and in the nuclear medicine field that many people in these fields honestly believe that the low

creases with altitude: One year of work (1,000 hours) as a flight attendant adds 1.19 chances per 1,000 flight attendants of developing a fatal cancer.³⁰ How many flight attendants are aware of this risk? Much of this type of ignorance about radiation and its risks can be alleviated by an explanation of the types of radiation significant to occupational exposure and of how reproductive injury is produced.

The types of ionizing radiation that are most harmful to exposed workers are X-rays, gamma rays, alpha particles, beta particles, and neutrons.³¹ X- and gamma-rays differ from alpha, beta, and neutron radiation in their fundamental nature: the former are electromagnetic and the latter are particulate.³²

Electromagnetic radiation consists of an electric field and a magnetic field that oscillate in planes perpendicular to each other and to the direction of the radiation's propagation.³³ The gamma ray is an electromagnetic pulse—a photon—that is emitted when an atomic nucleus, such as uranium, decays into a lower energy state.³⁴ The resulting radioactive elements have varying energies. If the source material decays in a manner that emits a large amount of energy, the gamma ray will be very penetrating. For example, fifteen centimeters of lead will stop only about fifty percent of some of the high-energy gamma rays that are encountered in occupational exposure.³⁵

The X-ray is a form of electromagnetic radiation that is produced whenever high-energy electrons suddenly release their energy.³⁶ Machines generate X-rays by accelerating electrons before directing them

levels of exposure permitted are without risk, which reflects that somehow the wrong message has been delivered, in spite of the fact that our regulatory program has been based on the prudent policy assumption that any amount of radiation has a finite probability of inducing a health effect, e.g., cancer. We brought out our concern that in the past the way the regulations were written and regulatory programs were established may be responsible for creating the impression among many workers that the levels of exposure permitted are completely without risk. We felt it should be made clear to workers that there is some risk.

Letter from Drs. Robert Minogue and Karl Goller, Office of Standards Development of the U.S. Nuclear Regulatory Comm'n, to John Gofman, *reprinted in* J. GOFMAN, *supra* note 3, at 590.

30. J. GOFMAN, *supra* note 3, at 575.

31. Since external irradiation of the whole body is the most common type of occupational exposure, many studies focus only on X-ray, gamma ray, and neutron sources due to their high penetrating power. *See, e.g.*, U.S. ENVTL. PROTECTION AGENCY, *supra* note 19, at 9. However, ignoring alpha and beta radiation would result in an underestimate of the occupational diseases attributable to inhaled, ingested, or absorbed sources of these types of radiation. *See, e.g.*, Sevcova, Sevc & Thomas, *Alpha Irradiation of the Skin and the Possibility of Late Effects*, 35 HEALTH PHYSICS 803 (1978) (reporting an excess of skin cancers in uranium miners exposed to alpha radiation).

32. *See supra* note 11.

33. *See* M. ECKER & N. BRAMESCO, RADIATION 13-19 (1981).

34. *Id.* at 17; E. POCHIN, NUCLEAR RADIATION: RISKS AND BENEFITS 9-10 (1983).

35. *See* E. POCHIN, *supra* note 34, at 151.

36. *See id.* at 4; M. ECKER & N. BRAMESCO, *supra* note 33, at 29.

against a target.³⁷ Although less energetic than gamma rays, X-rays have considerable penetrating power, as evidenced by their use as a medical diagnostic tool.³⁸

X-rays and gamma rays can be regarded as identical in nature, but different in origin. Aside from the difference in energy, X-rays and gamma rays interact identically with biological tissue.³⁹ The high penetrating power of both types of radiation poses a great threat to internal human organs.

Particulate radiation consists of the building blocks that compose the atom: protons, neutrons, and electrons.⁴⁰ Alpha radiation refers to positively charged particles—two protons and two neutrons—emitted from the nucleus of an atom. Alpha particles have a very low penetrating power and are completely absorbed by the skin.⁴¹ Unless a source is inhaled or ingested, alpha radiation poses little threat to internal organs.⁴²

Beta radiation consists of negatively charged electrons that are emitted at very high speeds from their atomic orbits.⁴³ Though able to travel farther than alpha particles, beta radiation still has a relatively low penetrating power.⁴⁴ It can penetrate the skin, but is completely absorbed by a thin metal foil.⁴⁵

External exposure to beta radiation poses little threat to reproductive functions, but many beta emitters also emit gamma rays as part of their decay pattern, thus inducing X-rays.⁴⁶ Beta emitters, therefore,

37. M. ECKER & N. BRAMESCO, *supra* note 33, at 29.

38. See E. POCHIN, *supra* note 34, at 4.

39. J. GOFMAN, *supra* note 3, at 24.

40. Most of the mass of any atom is contained in the nucleus, which carries a positive electric charge. The nucleus is a composite of particles known as protons and neutrons. The proton carries a charge equal and opposite to that of one electron; the neutron is electrically neutral. In orbit around the nucleus are one or more electrons that carry a negative charge and are held in orbit by electrical attraction to the nucleus. S. WEINBERG, *THE DISCOVERY OF SUBATOMIC PARTICLES* 3 (1983).

41. The range of alpha particles in tissue is approximately thirty to forty microns; a micron is one-millionth of a meter. This represents a tissue travel of three to four cell diameters. See J. GOFMAN, *supra* note 3, at 29.

42. *Id.* at 30.

43. *Id.* at 24.

44. *Id.*

45. J. HOGERTON, *IONIZING RADIATION* 3 (1966). The range of a beta particle is measured in millimeters. There are one thousand millimeters in a meter.

46. *Id.* While X-rays are mainly produced by the rapid deceleration of electrons in collision with a target in an X-ray machine, they can also be produced by beta irradiation of living tissues. Although secondary in nature, such X-irradiation is not inconsequential. For example, radium is a source of both gamma rays and alpha particles. As its hazards became known, the use of radium to illuminate watch dials was eliminated in favor of promethium, a beta-emitter. But the reduced health risk from this substitution may be overestimated. It is thought that the carrier of a pocket watch illuminated by promethium would receive a significant gonadal dose of X-rays generated by the beta irradiation of the watch case. See J. GOFMAN, *supra* note 3, at 578-79.

have an associated internal ionization potential, whether they are internalized or not.⁴⁷

Neutron radiation refers to neutrons emitted from the nucleus of an atom. Since neutrons have no charge, they are not repelled by the electrical fields of tissue. Thus, they are vastly more penetrating than charged particles having the same energy. This penetrating power poses severe shielding problems for those exposed to neutrons, and high density concrete walls several feet thick are necessary to protect personnel.⁴⁸ Without adequate protection, neutrons from external sources can reach and damage genetic material within the human body.⁴⁹

All forms of ionizing radiation affect living tissue through the same medium: electrically charged, subatomic particles. Alpha and beta radiation are directly ionizing forms of radiation: Their electrical charge causes ionizations in tissue through electrostatic attraction or repulsion with orbiting electrons.⁵⁰ Ionizing radiation that is not electrically charged, i.e., X-rays, gamma rays, and neutrons, is an indirectly ionizing form of radiation.⁵¹ Indirectly ionizing radiation fragments atoms to produce charged particles, which then act to ionize other atoms in the tissue.⁵² Any one ionization of an atom can produce biological changes that range from very minor to severe.⁵³

The most serious effects arise from ionizations within genetic material.⁵⁴ Chromosomes both regulate the function of cells and serve as the repository of the genetic material of future generations. Radiation-induced mutation⁵⁵ of a chromosome can result in a failure of cellular control mechanisms and can lead to cancer in the exposed individual.⁵⁶ If the mutation is present in a gamete,⁵⁷ the mutation can be passed to future generations. Chromosome breaks, one of the most common injuries

47. *Id.*

48. MCGRAW-HILL CONCISE ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 1151 (S. Parker ed. 1984).

49. *See generally* J. GOFMAN, *supra* note 3; *see also* Neel, Kato & Schull, *Mortality in the Children of Atomic Bomb Survivors and Controls*, 76 GENETICS 311 (1974) (authors assumed neutron exposure had a relative biological effectiveness of five times that of gamma rays for the types of genetic damage measured).

50. COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, NAT'L RES. COUNCIL, THE EFFECTS ON POPULATIONS OF EXPOSURE TO LOW LEVELS OF IONIZING RADIATION: 1980, at 12-13 (1980).

51. *Id.* at 13.

52. *Id.*

53. J. GOFMAN, *supra* note 3, at 57.

54. *See generally* J. GOFMAN, *supra* note 3 (reviewing the many diseases related to chromosomal aberrations).

55. Mutation refers to the process by which a gene undergoes a structural change. By extension, the term also denotes the modified gene resulting from, or the individual manifesting, the mutation. A mutagen is an agent capable of causing mutagenesis, i.e., changes in the genetic material that can be transmitted during cellular division.

56. *See generally* J. GOFMAN, *supra* note 3.

57. *See infra* note 70.

caused by radiation, can result in the deletion or translocation⁵⁸ of genetic material, both of which can cause serious reproductive disorders.⁵⁹

There are three broad categories of adverse health effects that result from occupational exposure to radiation: somatic, genetic, and *in utero*.⁶⁰ Somatic cells, as opposed to germ cells, are the cells that have differentiated into tissues and that are not involved in reproduction. Effects on somatic tissues can result from an individual's exposure at any time, either before or after birth. These effects range from cancer and leukemia to psychological stress.

Genetic effects involve damage to the chromosomes. When an individual has been irradiated prior to conceiving a child, chromosome damage in the egg or sperm can result in genetic abnormalities in the individual's descendants. These abnormalities may not become apparent for several generations.⁶¹

The third category, *in utero*, involves congenital or teratogenic⁶² effects that may result from irradiation of the fetus during gestation. These effects result from damage to the chromosomes of the fetus.

Somatic, genetic, and *in utero* radiation can all result in reproduc-

58. Deletion and translocation both refer to types of chromosomal damage caused by ionizing radiation. Deletion refers to the loss of a piece of chromosome following breakage and is one mechanism for radiation-induced loss of genetic material. Substantial evidence exists to show that the number of deletions produced is directly proportional to the dose of radiation delivered. Brewen, Preston, Jones & Gosslee, *Genetic Hazards of Ionizing Radiation: Cytogenetic Extrapolations from Mouse to Man*, 17 *MUTATION RES.* 245 (1973); Sasaki, *A Comparison of Chromosomal Radiosensitivities of Somatic Cells of Mouse and Man*, 29 *MUTATION RES.* 433 (1975). A review of the clinical severity of some of the prominent deletion syndromes can be found in J. GOFMAN, *supra* note 3, at 720-21.

Translocation describes the interchange of segments of genetic material between dissimilar chromosomes following breakage and refusion of reciprocal segments. Studies suggest that the frequency of translocations increase at a rate greater than that predicted by a linear dose-response relationship. Brown, *Linearity Versus Non-Linearity of Dose-Response for Radiation Carcinogenesis*, 31 *HEALTH PHYSICS* 231 (1976); Brown, *The Shape of the Dose-Response Curve for Radiation Carcinogenesis: Extrapolation to Low Doses*, 71 *RADIATION RES.* 34 (1977). Down's Syndrome, Patau's Syndrome, and Edward's Syndrome are associated with translocations. An inherited translocation has been shown to predispose offspring to a very high risk of kidney disease. Cohen, Li, Berg, Marchetto, Tsui, Jacobs & Brown, *Hereditary Renal-Cell Carcinoma Associated with a Chromosomal Translocation*, 301 *NEW ENG. J. MED.* 592 (1979).

59. See generally J. GOFMAN, *supra* note 2.

60. See *supra* note 6.

61. J. GOFMAN, *supra* note 3, at 707.

62. While both the terms "congenital" and "teratogenic" have temporal definitions, i.e., they both refer to effects on an individual that occur after conception but before birth, they differ in when the effects are clinically manifested. A congenital defect is a defect that exists at birth but is not clinically apparent until later in life. Higher than average rates of childhood leukemia and cancer are among the congenital effects of *in utero* irradiation. See Kato, *Mortality in Children Exposed to the A-Bomb While in Utero, 1945-1969*, 93 *AM. J. EPIDEMIOLOGY* 435 (1971). Thus the term congenital refers only to the time of injury.

A teratogen is any agent that raises the incidence of congenital malformation. A teratogenic defect differs from a congenital defect in being clinically apparent at birth.

tive deficiencies. For example, somatic effects include loss of libido,⁶³ impotence,⁶⁴ sterility,⁶⁵ and infertility.⁶⁶ Genetic effects include miscarriage and spontaneous abortion.⁶⁷ *In utero* irradiation can cause both birth defects and unusually high rates of childhood cancer and leukemia.⁶⁸ From a public health perspective, the genetic and *in utero* effects of irradiation constitute the most significant reproductive problems associated with occupational exposure.⁶⁹ This is true for effects resulting from both preconception and postconception irradiation.

The main reproductive health danger involved in preconception irradiation is damage to the germ cells,⁷⁰ spermatogonia⁷¹ and oocytes.⁷² Their genetic integrity ensures the viability and development of the fertil-

63. Steeno & Pangkahila, *Occupational Influences on Male Fertility and Sexuality*, 16 ANDROLOGIA 5 (1984).

64. *Id.*; Clifton & Bremmer, *The Effect of Testicular X-Irradiation on Spermatogenesis in Man: A Comparison with the Mouse*, 4 J. ANDROLOGY 387 (1983).

65. OFFICE OF TECHNOLOGY ASSESSMENT, 99TH CONG., 1ST SESS., REPRODUCTIVE HEALTH HAZARDS IN THE WORKPLACE 95 (1985).

66. COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 498.

67. Alberman, Polani, Roberts, Spicer, Elliot, Armstrong & Dhadiyal, *Parental Exposure to X-Irradiation and Chromosome Constitution in Their Spontaneously Aborted Foetuses*, 36 ANNALS HUM. GENETICS 185 (1972).

68. J. GOFMAN, *supra* note 3, at 708.

69. Somatic effects, while significant, are limited to the individual exposed. In contrast, genetic effects can be expressed in many offspring over several generations. For example, the increased risk of developing many forms of cancer is inheritable. *Id.* at 98-101. *In utero* exposures are of increased significance for two reasons. First, both somatic and genetic effects can result from *in utero* exposure. Second, to minimize the person-years lost to disease and early death, public health measures should focus on reducing exposures that occur early in life.

70. Germinal cells are those that produce eggs and sperm by repeated divisions of genetic material, i.e., oocytes in females and spermatocytes in males. The product of the germinal cells is the gametes, i.e., eggs and sperm, which are termed germ cells.

71. Spermatogonia are the primitive male germ cells that line the seminiferous tubules of the testes. At puberty, two major types of spermatogonia are present: type A, which generate other spermatogonia, and type B, which become mature sperm. During a male's reproductive life, the bulk of his sperm cells are in the spermatogonial stage. Spermatogenesis is the continuous process by which one spermatogonial germ cell divides repeatedly to form eight sperm. See generally Dixon, *Toxic Responses of the Reproductive System*, in CASARETT AND DOULL'S TOXICOLOGY (1980).

From a reproductive health perspective, exposure of the germinal cells is critical. Radiation injury to the genetic material contained in the spermatogonial cells can be repeatedly multiplied and passed to sperm that are produced long after exposure occurs. See generally J. GOFMAN, *supra* note 3, at 772.

72. In humans, germ cells are formed in females before birth. During the fetal period, primordial germ cells called oogonia proliferate and number between 300,000 and 400,000 in each ovary at birth. Shortly after birth, development of the oogonia is arrested and the immature eggs are called oocytes. About half the number of oocytes present at birth remain at puberty. By thirty years, the number is reduced to some 25,000. Only about 400 oocytes develop into mature eggs during the reproductive life of a woman. See Dixon, *supra* note 71, at 335-36.

Unlike the male, who produces eight sperm from each division of one spermatogonial cell, a female can produce but one egg from each oocyte. Thus, a woman's contribution to her offspring's genetic material must come from the finite number of oocytes that are extant at her

ized ovum into an embryo, fetus, normal child, and healthy adult. Irradiation of employees can damage the genetic material contained in the germ cells.⁷³

Radiation damage to germ cell chromosomes is cumulative over time.⁷⁴ A woman is born with a finite number of oocytes, and they are sensitive to radiation throughout her life. The oocytes that reach maturity late in a woman's reproductive life may have been dormant for as many as forty years. Cumulative radiation damage to the chromosomes of the oocytes can contribute to the increased frequency of germ cell mutations in older women.⁷⁵

In contrast, the male continuously produces sperm, whose sensitivity to radiation varies depending on their stage of development.⁷⁶ To a limited extent, the continuous production of sperm serves as a decontamination process by preventing cumulative exposure. However, the spermatogonial cells are very sensitive to the mutagenic effects of ionizing radiation.⁷⁷ Irradiation of the germinal epithelium may cause a mutation that results in the perpetual production of genetically damaged sperm.⁷⁸

Exposure of either sex prior to conception can cause genetic mutations that are expressed as congenital defects, developmental problems, birth defects, and increased childhood cancer and leukemia.⁷⁹ Moreover, genetically abnormal fetuses are more likely to suffer spontaneous abortion than normal fetuses.⁸⁰

Postconception irradiation poses the same somatic and genetic hazards to the parents as preconception irradiation. Despite significant alteration of the female biochemical profile during pregnancy, there is no

birth. Any agent that damages the oocytes can lead to a woman's reduced fertility as well as the expression of damaged genetic material in her offspring. *Id.*

73. See generally J. GOFMAN, *supra* note 3.

74. See *id.* at 47-49. A summary of studies of radiation-induced breast cancer succinctly states the conclusion that radiation damage is cumulative: "The observation that multiple low-dose exposures did not produce significantly fewer cancers per unit dose than less highly fractionated larger exposures suggests that radiation damage is cumulative and that highly fractionated X-irradiation may be as effective in inducing breast cancer as single or less fractionated exposures." Boice, Land, Shore, Norman & Tokunaga, *Risk of Breast Cancer Following Low-Dose Radiation Exposure*, 131 *RADIOLOGY* 589, 593 (1979).

75. Strobino, Kline & Stein, *Chemical and Physical Exposures of Parents: Effects on Human Reproduction and Offspring*, 1 *EARLY HUM. DEV.* 371, 378 (1978).

76. Dixon, *supra* note 71, at 334-35.

77. J. GOFMAN, *supra* note 3, at 772.

78. Germinal cells are those that produce gametes by repetitious division of the genetic material. "Epithelium" is a generic word describing any tissue that forms a surface of an organ. In conjunction, the phrase "germinal epithelium" refers to the tissue lining the interior of the testes that gives rise to sperm. The reproductive health threat resulting from genetic damage to the germinal epithelium is discussed *supra* note 71.

79. Strobino, Kline & Stein, *supra* note 75, at 371. See generally J. GOFMAN, *supra* note 3.

80. Kline, *Surveillance of Spontaneous Abortions*, 106 *AM. J. EPIDEMIOLOGY* 345 (1977).

evidence of an increased susceptibility to radiation at that time.⁸¹ However, unlike preconception irradiation, postconception irradiation also results in *in utero* exposure of the embryo/fetus.

In utero exposure may be particularly damaging because age-variable radiosensitivity is well documented: The young are most susceptible to radiation-induced cancer.⁸² During its periods of rapid tissue differentiation and growth, the embryo/fetus is very susceptible to radiation injury,⁸³ even at exposure levels well below those harmful to either parent.⁸⁴

Susceptibility to *in utero* exposure varies markedly with the stage of embryo/fetal development.⁸⁵ Before implantation of the fertilized egg, susceptibility to radiation is extremely high: Embryo death and miscarriage usually occur early in intrauterine development. If the embryo survives preimplantation irradiation, viable chromosome abnormalities⁸⁶ may result, such as imperfect development of the sexual apparatus⁸⁷ and Turner's Syndrome.⁸⁸ This period of high radiosensitivity spans the first two weeks after fertilization⁸⁹ and corresponds with the parents' ignorance of pregnancy. Unfortunately, this parental ignorance prevents the most effective implementation of workplace protective measures.

Exposure during the period of major organ development also presents a high risk of malformation.⁹⁰ This period spans the second to seventh week of gestation.⁹¹ Pregnancy cannot be detected by conventional methods until well into this period. If death of the embryo/fetus

81. Messite & Bond, *Reproductive Toxicology and Occupational Exposure*, in DEVELOPMENTS IN OCCUPATIONAL MED. 59, 61 (1980).

82. See J. GOFMAN, *supra* note 3, at 173, 268-70.

83. COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 492.

84. Warshaw, *Employee Health Services for Women Workers*, 7 PREVENTIVE MED. 385 (1978).

85. COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 480, 482.

86. If mutations are present in the genetic material of either the egg or the sperm at the time of fertilization, the resulting combination of genetic material can lead to severe results. First, the organism may not be viable, and death may occur in the early stages of embryonic cell division. Alternatively, the mutation may cause the death and abortion of the fetus at a later developmental stage. Congenital abnormalities may also result. Many serious chromosomal abnormalities do prove to be viable, e.g., Down's Syndrome babies. See generally J. GOFMAN, *supra* note 3.

87. Rugh & Grupp, *Effect of Low-Level X-Irradiation on the Fertilized Egg of the Mammal*, 25 EXPERIMENTAL CELL RES. 302 (1961).

88. COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 479.

Turner's Syndrome connotes a chromosomal disorder that is characterized clinically by short stature, sexual infantilism, and deformities of the chest, spine, skin, face, ears, eyes, and heart.

89. See *id.*

90. *Id.* at 479-80.

91. *Id.* at 480.

results, it is delayed until late in the prenatal or even the neonatal period.⁹² Nonfatal alterations produced during this period include sex-chromosome loss, severe physical deformities, and effects on germ cell populations and the central nervous system.⁹³

During the fetal period, lasting from the seventh week until birth, susceptibility to malformation decreases but nonetheless remains a risk.⁹⁴ Congenital effects not apparent at birth include fertility depression, reduced longevity, and incomplete development of the nervous system.⁹⁵ Susceptibility to disturbances in cerebral and gonadal development persist. For instance, some children exposed to radiation from the Hiroshima bomb between the seventh and fifteenth week of gestation later showed signs of microcephaly.⁹⁶

This simplified explanation of the types of occupationally significant radiation and of the mechanisms of radiation-induced reproductive damage should not lead the reader to believe that a simple regulatory approach to occupational exposure is either possible or acceptable. Physical and socioeconomic realities combine to make regulation of occupational radiation exposures that cause reproductive risks extremely complex.

The physical nature of radiation alone makes regulation difficult. The dangers posed by radiation are a complicated function of the type, source, and energy of the radiation; the type and susceptibility of the tissue exposed; the manner of exposure; and the type of health effect feared. As a result, a regulatory approach cannot be based simply on the penetrating power of the different types of radiation encountered in occupational exposure.

For example, neutrons can easily pass through the human body, whereas alpha particles are stopped by the first few cells.⁹⁷ This fact alone, however, does not render neutron radiation a greater occupational hazard or a greater regulatory concern. Contrary to intuition, the short path length of alpha particles may pose a greater biological danger. The health effects associated with radon, a gaseous alpha source that is a naturally occurring decay product of uranium illustrates this fact. Miners who inhale radon suffer alpha irradiation of the sensitive cells lining the lungs.⁹⁸ Because these cells completely stop all of the incident alpha particles, there is a much greater energy transfer to the lining of the lung per

92. *Id.* at 479-80.

93. *Id.* at 480.

94. *Id.*

95. *Id.*

96. Microcephaly is a condition in which an individual has an imperfectly developed, small head. Miller & Mulvihill, *Small Head Size After Atomic Irradiation*, 14 *TERATOLOGY* 355 (1976).

97. See *supra* text accompanying notes 40-49.

98. J. GOFMAN, *supra* note 3, at 446-50.

path length than there would be if the particle had penetrated these cells.⁹⁹ This greater linear energy transfer causes more ionizations in the sensitive tissue and hence an increased incidence of lung cancer in miners.¹⁰⁰

Another alpha-emitter that demonstrates the importance of the source of radiation, the manner of exposure, and the susceptibility of the exposed tissue is plutonium-239. Human organs have affinities for certain elements: bones collect calcium, the thyroid concentrates iodine, etc. Unfortunately, this biological affinity can increase the toxicity of alpha-emitting elements once they are internalized. For example, when plutonium-239 is deposited within the testes, the spermatogonial germ cells become the prolonged target of high-energy alpha radiation.¹⁰¹

These physical properties of radiation combine with socioeconomic considerations to further confound the problem of regulating occupational exposure. Among the chief socioeconomic concerns are the issues of sex discrimination and privacy. Should employers be allowed to discriminate in job placement because women suffer an increased susceptibility to breast cancer? In light of the sensitivity to radiation of the embryo/fetus, should a woman's job opportunities be limited according to her reproductive status? Should an employer have the right to know about issues as private as a woman's fertility, reproductive behavior, or pregnancy status?

A fundamental ethical issue is also linked to the regulation of radiation exposure. Many scientists do not believe that radiation injury exhibits a dosage threshold under which no injury will occur.¹⁰² Therefore, any standard that permits some exposure contemplates some injury. If there is no safe threshold of radiation exposure, radiation regulation necessarily reaches the ethical issue of balancing health against economic and other considerations. It is in the face of these realities that the Nuclear Regulatory Commission must regulate occupational exposure to radiation. Before comparing the NRC's current and proposed Standards for Protection Against Radiation, this Article examines the NRC's role in the regulation of radiation hazards and critiques the overall regulatory framework that has evolved.

II

FEDERAL REGULATORY RESPONSIBILITIES

Despite early awareness of the hazards of occupational exposure to radiation, Congress was slow in acting to protect workers' health. Even

99. For a discussion of the theory of linear energy transfer, see *id.* at 26-29.

100. *Id.* at 446-50.

101. Hunt, *Occupational Radiation Exposure of Women Workers*, 7 PREVENTIVE MED. 294, 306-07 (1978).

102. See generally J. GOFMAN, *supra* note 3.

the rapid development of nuclear technology during World War II, and the accompanying dramatic demonstrations of the biological destructiveness of nuclear weapons, did not elicit an immediate federal move to regulate public exposure to radiation. Indeed, the Atomic Energy Act of 1946,¹⁰³ which set up the basic structure for federal control of nuclear power, made no substantive statement about public or occupational health.¹⁰⁴ Instead, the 1946 Act demonstrated that Congress' principal concern was with preserving the government's monopoly on nuclear technology and securing the nuclear development program's secrecy.¹⁰⁵

Congress modified this policy with the passage of the Atomic Energy Act of 1954.¹⁰⁶ By that time, Congress had become intent on finding peaceful uses for atomic energy and sought to encourage private participation in the development of nuclear technology.¹⁰⁷ This new policy resulted in a substantial growth in the use of radioactive materials and a corresponding increase in the size of the exposed workforce. Congress anticipated this development: The 1954 Act represents the first substantive federal involvement in the protection of workers exposed to radiation.

Under the 1954 Act, Congress charged the Atomic Energy Commission (AEC) with enacting regulations to protect health,¹⁰⁸ and in 1957, the AEC issued its first Standards for Protection Against Radiation.¹⁰⁹ In 1959, the President underscored the growing concern over occupa-

103. Pub. L. No. 79-585, 60 Stat. 755 (1946) (amended 1954).

104. W. WOOD, *NUCLEAR SAFETY: RISKS AND REGULATION* 5 (1983).

105. The legislative history of the Atomic Energy Act of 1946 emphasizes these objectives:

Subject to the paramount objective of assuring the national defense and security, it is the purpose of the bill to direct the development of atomic energy in such a way as to improve the public welfare, increase the standard of living, strengthen free competition in private enterprise, and promote world peace. To carry out these purposes, the bill provides for Government programs of information, production, research, and development.

S. REP. NO. 1211, 79th Cong., 2d Sess. 1, *reprinted in* 1946 U.S. CODE CONG. & ADMIN. NEWS 1327, 1327-28.

106. Ch. 1073, 68 Stat. 919 (1954) (codified as amended at 42 U.S.C. §§ 2011-2296 (1982 & Supp. III 1985)).

107. *See* S. REP. NO. 1699, 83d Cong., 2d Sess. 9, *reprinted in* 1954 U.S. CODE CONG. & ADMIN. NEWS 3456, 3464:

This report has already summarized the considerations underlying the stringent prohibitions of the Atomic Energy Act of 1946 against private participation in atomic energy. It has also made clear that changing conditions now not only permit but require a relaxation of these prohibitions if atomic energy is to contribute . . . to our national security and progress.

. . . .

It is our firmly held conviction that increased private participation in atomic power development, under the terms stipulated in this proposed legislation, will measurably accelerate our progress toward the day when economic atomic power will be a fact.

108. 42 U.S.C. § 2201(b) (1982 & Supp. III 1985).

109. 10 C.F.R. pt. 20 (1957) (current version at 10 C.F.R. pt. 20 (1986)).

tional exposure to ionizing radiation by establishing the Federal Radiation Council:

The Council shall advise the President with respect to radiation matters directly or indirectly affecting health, including matters pertinent to the general guidance of executive agencies by the President with respect to the development by such agencies of criteria for the protection of humans against ionizing radiation applicable to the affairs of the respective agencies. The Council shall take steps designed to further the interagency coordination of measures for protecting humans against ionizing radiation.¹¹⁰

In 1960, the Federal Radiation Council issued its first guidelines for federal agencies to use in regulating occupational exposure to radiation.¹¹¹

From these modest beginnings, an elaborate federal regulatory structure has developed, principally in response to the enormous growth in the use of radioactive materials. Today, no single agency regulates radiation exposure of workers. Diverse statutory provisions scatter federal responsibility for radioactive materials among five executive departments,¹¹² an independent commission,¹¹³ and an agency.¹¹⁴ A 1977 congressional study on regulatory organization criticized this regulatory labyrinth as follows:

Federal regulation of radiation health and safety presents many of the same problems that marked control of toxic substances prior to this year. Responsibility is scattered and uneven, resulting in jurisdictional disputes and regulatory confusion. Too many agencies are charged with administering too many laws. And nobody has the clear ability to overview the total situation, or the power to guide and coordinate that dispersed authority. As a result coordination is not always systematic, and the extent of the risk is not fully understood, and some potentially significant hazards are not subject to any Federal controls at all. The field of radiation safety shows many deficiencies that typically mark a piecemeal ap-

110. Exec. Order No. 10,831, 24 Fed. Reg. 6669 (1959).

111. Radiation Protection Guidance for Federal Agencies, 25 Fed. Reg. 4402 (1960).

112. The departments and their statutory authority are: Department of Defense: 42 U.S.C. §§ 2121(b), 2140(b) (1982 & Supp. III 1985). Department of Energy: 42 U.S.C. § 7151 (1982 & Supp. III 1985); *see also* Exec. Order No. 12,038, 43 Fed. Reg. 4957 (1978), *amended by* Exec. Order No. 12,156, 44 Fed. Reg. 53,073 (1979), *reprinted in* 42 U.S.C. § 7151 app. at 1044 (1982 & Supp. III 1985). Department of Health and Human Services: 42 U.S.C. § 263(b) (1982), 21 U.S.C. §§ 360c-360k (1982). Department of Labor: 29 U.S.C. §§ 651-678 (1982 & Supp. III 1985), 30 U.S.C. §§ 801-962 (1982 & Supp. III 1985). Department of Transportation: 49 U.S.C. §§ 1801-1812 (1982).

113. The Nuclear Regulatory Commission's authority is derived principally from its predecessor agency, the Atomic Energy Commission. *See* 42 U.S.C. § 5841 (1982). The NRC's statutory authority is contained in the Atomic Energy Act, 42 U.S.C. §§ 2011-2296 (1982 & Supp. III 1985).

114. The Environmental Protection Agency was established and given the role of coordinating federal regulation of radiation hazards by Reorg. Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (1970), *reprinted in* 42 U.S.C. § 4321 app. at 502 (1982 & Supp. III 1985).

proach to Federal regulation.¹¹⁵

The divided federal regulatory responsibilities for exposure to radiation generally can be broken down into guidance and regulatory functions. The Environmental Protection Agency (EPA) is the federal agency responsible for the guidance of all federal agencies in the formulation of radiation standards.¹¹⁶ Pursuant to this authority, the EPA studies the hazards of occupational exposures to ionizing radiation to coordinate all federal rulemaking in this field.¹¹⁷ The NRC is the dominant federal agency in charge of regulating occupational radiation exposure. As this Article is primarily concerned with the regulation of radiation in the workplace, the following discussion focuses primarily on the structure and authority of the NRC. It also examines the NRC's jurisdictional interaction with other federal agencies involved in the regulation of occupational exposure to radiation.

The Energy Reorganization Act of 1974¹¹⁸ created the NRC¹¹⁹ and abolished the AEC.¹²⁰ The Atomic Energy Act of 1954 had given the AEC the conflicting roles of both promoting and regulating nuclear technology.¹²¹ The problems resulting from this duality generated a number of proposals to separate the regulatory from the promotional functions.¹²² The Reorganization Act established the NRC as an independent commission that inherited only the AEC's regulatory responsibilities.¹²³

The current mandate of the NRC is, by its own definition:

115. SENATE COMM. ON GOVERNMENTAL AFFAIRS, STUDY ON FEDERAL REGULATION, S. DOC. NO. 91, 95th Cong., 2d Sess. 326 (1977).

116. See *supra* note 114.

117. U.S. RADIATION POLICY COUNCIL, REPORT OF THE TASK FORCE ON OCCUPATIONAL RADIATION EXPOSURE REGULATIONS 8 (1980).

118. 42 U.S.C. §§ 5801-5841 (1982).

119. *Id.* § 5841.

120. *Id.* § 5814.

121. The Atomic Energy Act of 1954 declared that atomic energy was to be promoted to encourage "world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise." Atomic Energy Act of 1954, ch. 1073, § 1(b), 68 Stat. 919, 921 (current version at 42 U.S.C. § 2011 (1982)).

In contrast to this promotional directive, the Atomic Energy Commission was also directed to regulate atomic energy "to protect the health and safety of the public." *Id.* § 2(b), 68 Stat. at 921.

122. A strong conflict of interest is created by giving one agency the inconsistent mandate to both promote and regulate atomic energy. In 1961, a University of Michigan Law School study supported a complete separation of regulation from the AEC. See W. WOOD, *supra* note 104, at 23. A 1973 suit under the Freedom of Information Act, 5 U.S.C. § 552 (1982 & Supp. III 1985), allowed release of an AEC study estimating the consequences of a nuclear accident. The magnitude of the estimated damages gave rise to fears that the AEC was subordinating safety to the promotion of nuclear power. See E. ROLPH, NUCLEAR POWER AND THE PUBLIC SAFETY: A STUDY IN REGULATION 166 (1979).

123. 42 U.S.C. § 5841(f) (1982). The AEC's promotional functions were transferred to the newly created Energy Research and Development Administration. 42 U.S.C. § 5801(b) (1982) (amended by 42 U.S.C. §§ 7151(a), 7293 (1982)). The Energy Research and Develop-

[T]o assure that non-military uses of nuclear materials in the United States—as in the operation of nuclear power plants or in medical, industrial or research applications—are carried out with proper regard and provision for the protection of public health and safety and of the environment, the safeguarding of nuclear materials and facilities from theft and sabotage, and safe transport and disposal of nuclear materials and wastes.¹²⁴

The NRC derives its authority from three statutes: the Atomic Energy Act of 1954,¹²⁵ the Energy Reorganization Act of 1974,¹²⁶ and the Uranium Mill Tailings Radiation Control Act of 1978.¹²⁷ As noted above, the NRC's regulatory power is derived principally from the authority that Congress had granted to the AEC. All licensing and rulemaking functions of the AEC, conferred by the Atomic Energy Act of 1954, were transferred to the NRC by the Energy Reorganization Act of 1974. The Uranium Mill Tailings Radiation Control Act of 1978 expanded the NRC's jurisdiction by broadening the Atomic Energy Act's definition of "byproduct material" to include tailings and wastes associated with uranium and thorium mining.¹²⁸

Under these three statutes, the NRC's jurisdiction over human exposure to radiological hazards extends to the possession or use of any source,¹²⁹ byproduct,¹³⁰ or special nuclear materials.¹³¹ The NRC's jurisdiction runs with the materials encompassed by these Atomic Energy Act definitions, rather than to particular types of workplaces or facilities. The materials definitions are comprehensive: The NRC's regulations currently list 179 materials.¹³²

As a result, the NRC has comprehensive jurisdiction over radiation exposure in all occupational settings. If a component of a commercial

ment Administration was subsequently dissolved and its functions transferred to the Department of Energy. 42 U.S.C. §§ 7151(a), 7293 (1982).

124. 1984 NRC ANN. REP. 1 (1985).

125. 42 U.S.C. §§ 2011-2296 (1982 & Supp. III 1985).

126. 42 U.S.C. §§ 5801-5891 (1982).

127. 42 U.S.C. §§ 7901-7942 (1982).

128. 42 U.S.C. § 2014(e) (1982).

129. "The term 'source material' means (1) uranium, thorium, or any other material which is determined by the Commission . . . to be source material; or (2) ores containing one or more of the foregoing materials, in such concentration as the Commission may by regulation determine from time to time." 42 U.S.C. § 2014(z) (1982).

130. The term 'byproduct material' means (1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. 42 U.S.C. § 2014(e) (1982).

131. "The term 'special nuclear material' means (1) plutonium, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission . . . determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing. . . ." 42 U.S.C. § 2014(aa) (1982).

132. See NRC Standards for Protection Against Radiation, 10 C.F.R. § 20 app. C (1986).

product is source material (such as the uranium used in ceramic dyes, the thorium used in welding rods, or the tritium used to illuminate clocks) or is reactor produced¹³³ (such as the americium used in smoke detectors), then the NRC regulates the workplace in which it is used. Thus, the NRC, with its comprehensive regulatory mandate over nuclear power plants, also finds smoke detector and ceramic manufacturing plants within its charge.¹³⁴ Other regulated workplaces include nuclear fuel processors, uranium mines and mills, and all industrial, manufacturing, medical, and pharmaceutical facilities that use the materials defined by the Atomic Energy Act.¹³⁵

There are five program offices within the NRC that implement the Commission's regulatory responsibilities for health and safety.¹³⁶ The Office of Nuclear Reactor Regulation licenses the construction and operation of nuclear reactors and the handling of nuclear material.¹³⁷ This office licenses reactors in a two-phase process: It issues the first license prior to construction and the next, an operating license, before fuel can be loaded.¹³⁸ Both existing and proposed reactors are evaluated for the health, safety, and environmental impacts of facilities and sites.¹³⁹ The Office of Nuclear Material Safety and Safeguards oversees the processing, transporting, and handling of nuclear materials.¹⁴⁰ This Office reviews license provisions for safety and recommends research on safety issues.¹⁴¹ The Office of Nuclear Regulatory Research develops policy options and investigates safety issues as directed by the Commissioners.¹⁴² The Office of Standards Development recommends standards, in the form of regulations and regulatory guides, designed to protect the public from radiological hazards.¹⁴³ The Office of Inspection and Enforcement ensures licensee compliance with NRC regulations, orders, and license conditions.¹⁴⁴

133. In addition to the naturally occurring radioactive elements, there are a number of artificially produced radioactive elements. For example, when aluminum is bombarded with alpha-particles, a neutron is emitted from the aluminum and a radioactive isotope of phosphorus is produced. Many artificially produced radionuclides are inevitable byproducts of a nuclear chain reaction maintained by the bombardment of uranium-238 by neutrons in nuclear power reactors. One such byproduct, americium-241, is central to the function of smoke alarms. Another byproduct, plutonium-239, was used in the bomb that devastated Nagasaki. See generally J. GOFMAN, *supra* note 3, at 469-74.

134. See SENATE COMM. ON GOVERNMENTAL AFFAIRS, *supra* note 115, at 338.

135. See 42 U.S.C. § 2014 (1982).

136. For a detailed description of the organization of the NRC, see generally W. WOOD, *supra* note 104, at 29; 1984 NRC ANN. REP., *supra* note 124.

137. See 10 C.F.R. § 1.61 (1986).

138. 1984 NRC ANN. REP., *supra* note 124, at 190.

139. See 10 C.F.R. § 1.61 (1986).

140. See *id.* § 1.60.

141. See *id.*

142. See *id.* § 1.62.

143. See *id.* § 1.63.

144. See *id.* § 1.64.

Thus, the NRC implements its statutory authority in three principle ways: It conducts licensing proceedings, engages in rulemaking, and issues regulatory guidelines. The NRC also has the authority to delegate limited regulatory power to state radiation control programs.¹⁴⁵

The NRC has broad authority to regulate by license all aspects of nuclear technology.¹⁴⁶ It licenses Atomic Energy Act materials on a cradle-to-grave basis: Licenses are necessary to mine, distribute, possess, use, transport, and dispose of nuclear material. In all licensing proceedings, the NRC establishes the minimum criteria requisite to the issuance of a license,¹⁴⁷ and it can condition the license on terms that force the licensee to comply with all NRC rules, regulations, and orders.¹⁴⁸

Facilities that produce or use nuclear material also undergo an extensive two-step licensing process. A license is required at both the construction and operation stages.¹⁴⁹ The NRC staff reviews safety aspects at each stage. At the operating stage, the NRC issues a license with restrictions and conditions it has deemed necessary for the safe operation of the facility. Throughout the licensing process, there is a strong presumption that the facility can be built and operated with acceptable safety. In fact, the NRC has never denied an operating license to a constructed nuclear facility.¹⁵⁰ Nevertheless, NRC licensing proceedings influence the development of important elements of nuclear safety regulation.¹⁵¹

The NRC also has broad authority to promulgate regulations and uses that authority in a coordinated manner with its licensing procedures.¹⁵² Many regulatory decisions must be made on an ad hoc basis during the licensing process because of the complexity of nuclear technology and its continuing development. Many of the effects of the use of nuclear technology, however, are independent of the particular use made of the radioactive materials. For these types of applications, broad, general rules can be formulated by the NRC and licenses can be conditioned

145. 42 U.S.C. § 2021 (1982).

146. Authority to license possession of source, byproduct, and special nuclear material is found, respectively, in 42 U.S.C. §§ 2093(a), 2111, 2073(a) (1982). Furthermore, licenses are required before any person can transfer or receive any equipment capable of producing or utilizing special nuclear material. 42 U.S.C. § 2131 (1982). This latter requirement applies to a wide range of commercial, industrial, medical, and research facilities.

147. 42 U.S.C. §§ 2073(b), 2093(b), 2111 (1982).

148. 42 U.S.C. § 2233 (1982).

149. See W. WOOD, *supra* note 104, at 29.

150. See *id.* at 30.

151. See *id.* at 29. At both the preconstruction and preoperation levels, the licensing process involves a public hearing with the availability of appeal to the Atomic Safety and Licensing Appeal Board, then to the Commission, and finally to the federal courts. *Id.* These proceedings are adversarial and tend to focus on safety issues: the sufficiency of evacuation plans, operator training, earthquake resilience, emergency core-cooling, and backfitting of new technology.

152. 42 U.S.C. § 2233 (1982 & Supp. III 1985).

on compliance with these regulations. Health and safety issues are particularly well suited for resolution through rulemaking. For example, an exposure to the same dose of radiation has an identical effect on workers regardless of whether the exposure occurred in a nuclear power plant or a uranium mine. Limits on occupational exposure can thus be set by regulation for all facilities that use Atomic Energy Act materials.

In addition to regulations, the NRC issues regulatory guides. Regulatory guides are used for a variety of purposes.¹⁵³ Some guides describe methods for implementing specific parts of the NRC's regulations. Others advise applicants of the information the NRC needs in reviewing license applications. Still others describe NRC staff techniques used to evaluate specific situations. The primary importance of regulatory guides, however, stems from their description of acceptable methods of licensee compliance with NRC regulations.¹⁵⁴

In contrast with its procedure for promulgating regulations, which must conform with the Administrative Procedure Act,¹⁵⁵ the NRC issues its regulatory guides through informal procedures.¹⁵⁶ As a result, the guides are not legally binding. However, the expense to the licensee of demonstrating alternative methods of compliance provides strong incentives for the licensee to adopt the NRC's methods.¹⁵⁷ Further, an NRC advisory committee has described the guides as "excessively prescriptive."¹⁵⁸ As a result, the licensee has little leeway for developing alternative methods of promoting safety.¹⁵⁹

The NRC also has the authority to relinquish specific regulatory powers to a state by written agreement.¹⁶⁰ Before entering an agreement with a state, the Commission must determine that the state radiation protection program is compatible with that of the NRC.¹⁶¹ To be compatible, agreement state programs must effectively incorporate the NRC's regulations concerning occupational safety and health.¹⁶² By 1984, twenty-seven states had assumed regulatory responsibility over by-product and source material as well as over small quantities of special nuclear material.¹⁶³ These states have issued some 13,100 radioactive

153. See generally 1984 NRC ANN. REP., *supra* note 124, at 158, 208.

154. W. WOOD, *supra* note 104, at 28.

155. 5 U.S.C. §§ 551-553 (1982 & Supp. III 1985); see 42 U.S.C. § 2239 (1982).

156. The guides are issued in draft form for public comment before final staff review and official commitment to the position embodied in the guide. See 1984 NRC ANN. REP., *supra* note 124, at 208.

157. See W. WOOD, *supra* note 104, at 28-29.

158. ADVISORY COMM. ON REACTOR SAFEGUARDS, U.S. NUCLEAR REGULATORY COMM'N, A REVIEW OF NRC REGULATORY PROCESSES AND FUNCTIONS 8 (1980).

159. See W. WOOD, *supra* note 104, at 29.

160. 42 U.S.C. § 2021(b) (1982).

161. 1984 NRC ANN. REP., *supra* note 124, at 123.

162. *Id.*

163. The NRC may not delegate responsibility for special nuclear material in quantities

material licenses, constituting about sixty percent of all radioactive material licenses issued in the United States.¹⁶⁴

Because special nuclear material is used in weapons, the NRC does not, except on a limited basis, delegate responsibility for that class of materials.¹⁶⁵ The NRC also does not delegate its responsibility for the export or import of nuclear materials or facilities¹⁶⁶ or for certain methods of disposal of nuclear materials.¹⁶⁷

While the NRC and several other agencies have statutory authority to set and enforce standards for exposure to radiation, the EPA provides overall federal guidance. Upon its creation, the EPA inherited functions from both the Federal Radiation Council and the AEC.¹⁶⁸ From the Federal Radiation Council, the EPA inherited responsibility for providing regulatory guidance for and interagency coordination of the development of standards to protect humans from ionizing radiation.¹⁶⁹ The responsibilities of the AEC were transferred to the EPA

to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations of quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.¹⁷⁰

Under this authority, the EPA studies the hazards of exposure to radiation, formulates guidelines for other regulatory agencies, and promulgates radiation standards applicable to the general environment.¹⁷¹ Most federal regulations are consistent with the EPA's guidance.¹⁷²

The EPA's authority over radiological hazards, however, does not extend to the workplace. While it inherited authority over radiation in the general environment, the EPA was not granted authority over occupational exposure to radiation.¹⁷³ Its jurisdiction thus does not extend to workplaces and facilities where Atomic Energy Act materials are used,

sufficient to form critical mass, 42 U.S.C. § 2021(b)(4) (1982), or for the construction or operation of any facility or device capable of using special nuclear material, *id.* § 2021(c)(1).

164. 1984 NRC ANN. REP., *supra* note 124, at 123.

165. 42 U.S.C. § 2021(b)(4), (c)(2)-(4).

166. *Id.* § 2021(c)(2).

167. *Id.* § 2021(c)(3)-(4).

168. Reorg. Plan No. 3 of 1970, *supra* note 114.

169. See Exec. Order No. 10,831, *supra* note 110.

170. Reorg. Plan No. 3 of 1970, *supra* note 114, § (a)(6).

171. See generally U.S. RADIATION POLICY COUNCIL, REPORT OF THE TASK FORCE ON OCCUPATIONAL RADIATION EXPOSURE REGULATIONS (1980).

172. Radiation Protection Guidance for Federal Agencies, 3 Fed. Reg. 4402 (1970).

173. Reorg. Plan No. 3 of 1970, *supra* note 114, § 2(a)(3). Responsibility for occupational radiation regulation was left under the aegis of the former Department of Health, Education and Welfare within the Bureau of Radiological Health of the Environmental Health Service.

as these facilities fall under the jurisdiction of the NRC.¹⁷⁴ The NRC is therefore not bound by the EPA's guidance¹⁷⁵. The EPA's standards are applicable, however, to radiation from AEC materials that emanate from an NRC-regulated facility into the general environment.¹⁷⁶

Several federal agencies do share responsibility with the NRC for regulating occupational exposure to radiation. This situation has resulted in a piecemeal approach to radiation safety in the workplace and presents a complicated jurisdictional picture. The Department of Energy (DOE), the Department of Defense (DOD), and the Department of Labor (DOL) all have regulations designed to directly limit certain exposures.¹⁷⁷ The Department of Health and Human Services (DHHS) and the Department of Transportation (DOT) indirectly regulate exposure.¹⁷⁸ Each agency's interaction with the NRC raises particular jurisdictional problems and has resulted in different interagency solutions.

Both the DOE and the DOD are exempt from NRC jurisdiction in the handling of Atomic Energy Act materials. The Energy Reorganization Act of 1974¹⁷⁹ transferred the AEC's regulatory authority over certain research facilities—including those involved in weapons¹⁸⁰ and military vessel applications¹⁸¹—to the Administrator of the Department of Energy.¹⁸² The Atomic Energy Act excludes the DOD from NRC licensing requirements.¹⁸³ As a result, these Departments are responsible for regulating health and safety at their own and at contractor-operated facilities. Both Departments have adopted occupational exposure regulations.¹⁸⁴

Two agencies within the DOL have authority to protect workers from radiation: the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA). The

174. Atomic Energy Comm'n, AEC-Licensed Facilities Memorandum of Understanding, 38 Fed. Reg. 24,936 (1973).

175. See SENATE COMM. ON GOVERNMENTAL AFFAIRS, *supra* note 115, at 329-32.

176. *Id.*

177. The Department of Energy has codified regulations dealing with the radiological occupational safety programs of its contractors at 48 C.F.R. § 970.23 (1985). Regulations from the Department of Defense dealing with exposures from atmospheric weapons testing are codified at 32 C.F.R. § 218 (1986). Within the Department of Labor, the Occupational Safety and Health Administration (OSHA) has codified regulations on ionizing radiation at 29 C.F.R. § 1910.96 (1985); the Mine Safety and Health Administration has codified regulations on radon exposure at 30 C.F.R. § 57.5037 (1986).

178. The Food and Drug Administration has promulgated regulations to limit radiation emanating from electronic products. 21 C.F.R. § 1000.3 (1986). The DOT has promulgated regulations concerning the transport of nuclear materials. 49 C.F.R. § 172 (1985).

179. 5 U.S.C. §§ 5313-5316, 5801-5891 (1982 & Supp. III 1985).

180. *Id.* § 5814(d).

181. 42 U.S.C. § 7158 (1982). These transfers were accomplished through the intermediate agency of the Energy Research and Development Administration.

182. *Id.* § 7151.

183. 42 U.S.C. § 2140(b) (1982).

184. See *supra* note 177.

Occupational Health and Safety Act of 1970¹⁸⁵ gave OSHA broad authority to regulate hazardous occupational exposures. However, OSHA's authority does not extend to workplaces covered by other federal agencies,¹⁸⁶ and it is therefore preempted by NRC regulation of occupational exposure to radiation. OSHA has published regulations limiting exposure to radiation that comes from sources other than Atomic Energy Act materials, including naturally or accelerator-produced radioactive materials, X-rays in medical or industrial uses, and electronic devices that produce ionizing radiation.¹⁸⁷

The Federal Mine Safety and Health Act of 1977¹⁸⁸ gave MSHA broad authority to promulgate and enforce standards to protect miners from various hazards, including certain radioactive minerals. MSHA regulations apply to miners who are exposed to radiation by working with uranium, phosphate, coal, and other radioactive materials. The regulations also cover workers in the uranium milling and mining industry.¹⁸⁹

In the case of uranium mining and milling, MSHA and the NRC have overlapping jurisdiction. In recognition of this overlap, the Agencies have agreed to exercise their statutory responsibilities in a coordinated manner. The NRC has assisted MSHA in the development of health standards compatible with NRC regulations, and the Agencies exchange information and coordinate inspection procedures.¹⁹⁰

DHHS regulates sources of radiation that indirectly affect occupational exposure. The Radiation Control for Health and Safety Act of 1968¹⁹¹ authorizes the promulgation and enforcement of performance standards to control radiation emissions from electronic products.¹⁹² Within DHHS, the Food and Drug Administration has oversight responsibility for these regulations.¹⁹³

Finally, the DOT indirectly regulates occupational exposure through its packaging, storage, and transport regulations under the authority conferred by the Hazardous Materials Transportation Act of 1966.¹⁹⁴ The DOT thus regulates interstate transportation of all radio-

185. 29 U.S.C. §§ 651-678 (1982 & Supp. III 1985).

186. *Id.* § 653(b)(1).

187. 29 C.F.R. § 1910.96 (1985).

188. 30 U.S.C. §§ 801-962 (1982 & Supp. III 1985).

189. 30 C.F.R. § 57.5037 (1986).

190. Nuclear Regulatory Commission-Mine Safety and Health Administration Memorandum of Understanding, 45 Fed. Reg. 1315 (1980).

191. 42 U.S.C. §§ 263b-263n (1982).

192. Electronic products that emit ionizing radiation include video display terminals; televisions; X-ray machines in medical, baggage check, and industrial applications; electron microscopes; neutron generators; and accelerators.

193. *See* 21 C.F.R. § 1000.3 (1986).

194. 49 U.S.C. §§ 1801-1812 (1982).

active materials,¹⁹⁵ including Atomic Energy Act materials. This authority overlaps with NRC authority to regulate transportation of nuclear materials. This jurisdictional overlap has long been the subject of an interagency agreement.¹⁹⁶

Two fundamental questions arise regarding the current federal approach toward regulation of occupational exposures to radiation. First, does the current jurisdictional structure provide the most efficient regulation of occupational radiation exposure? Second, are the harmful impacts of frequent and widespread exposures to radiation being properly assessed and minimized under the existing system?

The criticism that "too many agencies are charged with too many laws"¹⁹⁷ oversimplifies the complexity of the jurisdictional question. The choice in structuring a regulatory system is between having many agencies whose jurisdiction runs vertically—i.e., a consumer product agency regulating radiation-emitting products, an environmental agency regulating environmental radiation, etc.—or establishing one agency whose jurisdiction runs horizontally—i.e., a unitary body with jurisdiction over all sources and exposures to radiation. For sound reasons, Congress has chosen the vertical-jurisdiction, multiagency approach.

A unitary agency approach would increase jurisdictional complexity and result in wasted duplication of regulatory expertise and efforts rather than streamline the existing system. For example, consider the manufacturer of radiopharmaceuticals¹⁹⁸ whose products are regulated both because they are radioactive and because they may be hazardous for other reasons. The unitary approach would require that one agency have expertise in the occupational, environmental, transportation, consumer product, and disposal safety aspects of the manufacturer's business to regulate the occupational exposures to radiation. Such expertise is already housed in other independent agencies in the vertical-jurisdiction structure. Moreover, these separate agencies would continue to exist to regulate the hazards of the manufacturer's products that are unrelated to their radioactivity.

Thus, the unitary agency and OSHA would both regulate occupational health; the unitary agency and the EPA would both regulate environmental aspects; the unitary agency and the FDA would both regulate product safety aspects, and so on with every aspect of the manufacturer's

195. See 49 C.F.R. § 172 (1985).

196. The Memorandum of Understanding between the NRC and DOT prevents duplication of effort by allocating responsibility for accident management and for the development of safety standards for packages, carriers, carrier loading and unloading, and for carrier personnel. Transportation of Radioactive Materials, Atomic Energy Commission Memorandum of Understanding, 38 Fed. Reg. 8466 (1973).

197. SENATE COMM. ON GOVERNMENTAL AFFAIRS, *supra* note 115, at 326.

198. Radiopharmaceuticals are chemical compounds, medicines, or drugs that are intentionally rendered radioactive to allow experimentation or diagnosis and treatment of diseases.

business. The result would be fractionated regulatory expertise and increased jurisdictional complexity.

The present operation of the vertical jurisdiction system is not, however, optimal. The chief inadequacy in the current jurisdictional mosaic is the lack of any coherence in the structure. No one agency has sufficient authority to oversee all aspects of radiation safety, to coordinate federal actions, or to delegate responsibility to and solicit responses from the various regulatory bodies. While the EPA did inherit a guidance role from the Federal Radiation Council, this function has been viewed solely in terms of providing advice to the executive branch.¹⁹⁹ The EPA also does not have the legal authority to command compliance from the various federal regulatory bodies according to its regulatory guidance.²⁰⁰

Where occupational exposure to radiation is concerned, the lack of federal focus is even more pronounced. The EPA does not have jurisdiction over the occupational aspects of radiation.²⁰¹ Even if the various regulatory bodies voluntarily were to acquiesce to the EPA serving as a coordinator in the multiagency structure, the EPA has neither the expertise nor the mandate to address occupational exposures.

Rather, the expertise regarding occupational exposures resides in the NRC, OSHA, and in the National Institute of Occupational Safety and Health (NIOSH) of DHHS. These bodies operate as coequals, however, and no hierarchy exists through which problems identified by one body will be communicated to the others and through which regulatory solutions implemented by one body will be coordinated with and implemented by the others. One federal agency should have the statutory authority to focus this widely scattered expertise and coordinate all the regulatory bodies to ensure that the harmful impacts of occupational radiation exposure are both identified and minimized.

The proposed revisions of the Standards for Protection Against Radiation do not address these problems in the regulatory framework. Nonetheless, they represent a significant advance in the effort to protect workers from radiation hazards in the workplace. Moreover, given the NRC's preeminence in the regulatory structure outlined above, the NRC's new approach may have a significant impact on the manner in which other federal agencies exercise their regulatory authority over radiation hazards. The succeeding Sections of this Article take a close look at the NRC's proposed Standards and their further implications.

199. The EPA's charge was that given to the Federal Radiation Council. *See supra* text accompanying note 110.

200. *See generally* SENATE COMM. ON GOVERNMENTAL AFFAIRS, *supra* note 115, at 25-80.

201. Reorg. Plan No. 3 of 1970, *supra* note 114, § 2(a)(3).

III

NRC STANDARDS FOR PROTECTION AGAINST RADIATION

The NRC has recently proposed revision of the Standards for Protection Against Radiation²⁰² as a result of a fundamental change in the rationale underlying the current Standards. The current Standards²⁰³ are derived from those first developed in the late 1950's.²⁰⁴ When first promulgated, the standards limiting occupational radiation exposure included what was thought to be a "very substantial margin of safety for exposed individuals."²⁰⁵ These standards were predicated on the theory that a threshold dose existed under which exposure would cause no adverse health effects. Subsequent experience with the increased use of radiation led to a rejection of the threshold-dose hypothesis.²⁰⁶ If no threshold dose exists, exposures once thought completely safe will actually result in negative health consequences.

With the repudiation of the threshold concept, the current Standards for Protection Against Radiation lost their theoretical foundation. Despite this new awareness of increased risks from exposure to low doses of radiation, the NRC did not immediately seek to develop a new theoretical basis for the Standards. Instead, the NRC allowed the current occupational exposure limits to evolve through an implicit balancing of the danger of negative health consequences against the perceived benefits of the use of radioactive materials.²⁰⁷

The proposed revisions of the Standards for Protection Against Radiation represent an explicit recognition by the NRC that the threshold-dose concept no longer serves as an appropriate basis for setting occupational exposure limits. In contrast to the current implicit balancing performed by the NRC, the proposed Standards would formally bifurcate the process of formulating exposure limits. The revisions allow for separate consideration of (1) the level of risk associated with various exposure levels and (2) the social acceptability of the risks presented. "In the proposed revision, limits are derived explicitly by quantifying risk, and then by judging the acceptability of the risk through a comparison of risks experienced by workers in industries not involving radiation exposure or a comparison of risks normally encountered by the general public."²⁰⁸

202. 50 Fed. Reg. 51,992 (1985) (to be codified at 10 C.F.R. pt. 20) (proposed Dec. 20, 1985).

203. 10 C.F.R. pt. 20 (1986).

204. Compare 22 Fed. Reg. 548 (1957) with 10 C.F.R. pt. 20 (1986).

205. 22 Fed. Reg. 548 (1957).

206. See J. GOFMAN, *supra* note 3, at 370; COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 22; GENERAL ACCOUNTING OFFICE, PROBLEMS IN ASSESSING THE CANCER RISKS OF LOW-LEVEL IONIZING RADIATION EXPOSURE 39 (1981).

207. In the NRC's own words, "[l]imits were derived by implicit judgments on health effects associated with the use of licensed materials." 50 Fed. Reg. at 51,992.

208. *Id.* at 51,993.

The following subsections explain the conceptual bases that underpin the current Standards for Protection Against Radiation and outline the application of those regulations in the occupational context. The current Standards are also critically evaluated for their impact on worker health in general and for their specific effect on reproductive health. Finally, the NRC's past failure to take regulatory account of the radiosensitivity of the embryo/fetus is explored in view of the scientific community's historic call for increased regulatory protection. Section IV then analyzes the proposed Standards for their impact on worker health in general and on reproductive health in particular.

A. *Current Regulatory Assumptions*

The current Standards²⁰⁹ do not explicitly address reproductive health. However, one can infer from the content of the regulations that the NRC considered some aspects of reproductive health during the development of the current Standards. For example, the regulations deal with the sensitivity of youth,²¹⁰ the various risks associated with cumulative dose,²¹¹ and the susceptibility of gonads to radiation.²¹² However, no provisions deal explicitly with the exposure of pregnant women or the increased radiosensitivity of the embryo/fetus. Thus, the current NRC regulations must carefully be disassembled to determine their implicit effect on the reproductive health of workers and the adequacy with which they address reproductive concerns.

An understanding of the theoretical underpinnings of and the assumptions built into the NRC's regulation of occupational exposure aids in interpreting the Standards. What is most disturbing about the current Standards is that they are not based on a clear, health-risk rationale.²¹³ When originally promulgated, the Standards "provided what, at that time, was considered to be 'a very substantial margin of safety for exposed individuals,' which infers a threshold value for health damage or no observable clinical effects."²¹⁴

209. The current NRC regulations for protecting workers are set forth in 10 C.F.R. pts. 19 and 20 (1986). Although only part 20 bears the title "Standards for Protection Against Radiation," part 19 is directly related to part 20 because it establishes requirements for notice, instructions, and reports by licensees to employees who are exposed to radiation. Required procedures include instructions to the workforce concerning radiation health protection as well as reports to individual workers detailing their exposures. Part 20 defines permissible doses, levels, and concentrations to which employees can be exposed. Part 20 also outlines precautionary procedures, including radiation surveys and personnel monitoring. Compliance with both parts 19 and 20 is a mandatory condition of all NRC licenses. 10 C.F.R. §§ 19.2, 20.2 (1986).

210. *Id.* § 20.104.

211. *Id.* § 20.101(b).

212. *Id.*

213. 50 Fed. Reg. 51,992 (1985).

214. *Id.* (quoting 22 Fed. Reg. 548 (1957)).

With the demise of the threshold-dose hypothesis as a rationale for exposure limits, however, there was no concurrent effort to develop an alternative basis for the Standards. As was recently recognized by the NRC:

None of these factors, upon examination, suggest that there have been significant increases in radiation exposure or in health detriment of workers or members of the public since 1957; on the contrary, protection has been good and has improved over the twenty plus years since the Commission established its regulatory program. This may be partially due to a substantial number of revisions of part 20 to reflect technical and administrative changes. However, these revisions have not kept the regulations in accord with more recent recommendations of scientific organizations . . . to improve overall protection and establish a clear, health-risk rationale. The basic approach to radiation protection in the original regulation (i.e., margin of safety) has been retained throughout the previous revisions without any effort to relate the approach more directly to any associated health risk. Limits were derived by implicit judgments on health effects associated with the use of licensed materials.²¹⁵

The Commission's "implicit judgments on health effects"²¹⁶ have been formulated under three interacting but separate concepts: the linear-dose response assumption, cost-benefit analysis, and the "as-low-as-is-reasonably-achievable" (ALARA) recommendation.

The linear dose-response assumption is a result of the inability of current analytical methods to define the pathological effects of either acute or chronic exposure to low doses of radiation. Given the absence of low dose correlations between exposure and effect, the NRC now operates on the assumption that there is no threshold dose below which radiation damage will not occur.²¹⁷ Most authorities have thus adopted the conservative hypothesis of a linear relationship between dose and biological effect, even at very low doses.²¹⁸ This means that each increment of radiation exposure, however small, is currently assumed to result in an increment of health risk. This assumption influences the NRC's approach to the formulation of occupational radiation standards.²¹⁹

The NRC makes extensive use of cost-benefit analysis²²⁰ in its devel-

215. 50 Fed. Reg. at 51,992.

216. *Id.*

217. See, e.g., OFFICE OF STANDARDS DEVELOPMENT, U.S. NUCLEAR REGULATORY COMM'N, REGULATORY GUIDE 8.13, INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE (1975) (control of radiation is based on the assumption that any exposure, no matter how small, involves some risk).

218. See letter of transmittal prefacing COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50.

219. See J. GOFMAN, *supra* note 3, at 370.

220. For a definition of cost-benefit analysis and an examination of the propriety of its use by regulatory agencies involved in the resolution of health and safety issues, see Baram, *Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisionmaking*, 8 *ECOLOGY L.Q.* 473 (1980).

opment of exposure limits governing the use of radioactive materials.²²¹ In the context of the NRC's regulatory role, this use of cost-benefit analysis is troubling. The NRC clearly has a mandate to ensure the safe utilization of nuclear materials.²²² However, it is debatable whether the NRC should consider economic factors in developing standards to protect health.²²³ Rather than establishing exposure standards purely on the basis of health considerations and then using economic analysis to determine the most cost-effective means of reaching those standards, the NRC's use of cost-benefit analysis in the development of standards necessarily dilutes the weight given to health considerations.²²⁴ As a result, the NRC does not set standards to protect health, but instead sets standards to protect whatever degree of health is deemed affordable.

Perhaps this type of approach necessarily accompanies any attempt to regulate toxicants that are associated with economically beneficial activities. However, reliance on cost-benefit analysis requires the monetization of human health and lives.²²⁵ If this analytical evil is indeed necessary, the monetization by administrative bodies of incommensurates such as human life, health, and the increased risk of disease or fetal deformity should be explicit.

The danger of the NRC's use of cost-benefit analysis in the formulation of occupational exposure standards stems not only from the lack of explicit quantification of health benefits but also from the lack of a clear, health-based rationale for the occupational radiation exposure limits. As the threshold-dose hypothesis lost its force, the current Standards lost their health-based rationale. Without such a rationale, it is difficult for undefined and unfocused health considerations to offset economic considerations, especially when the economic benefits of a particular activity are perceived to be great. The inevitable result is that cost-benefit analy-

221. *Id.* at 499; *see also* 10 C.F.R. § 50 app. 1, § II(D) (1986) (the NRC requires a figure of \$1,000 per total body man-rem to be used by a licensee in performing cost-benefit analysis of the efficacy of control devices that limit the exposure of populations near a reactor).

222. 42 U.S.C. § 2201(b) (1982 & Supp. III 1985) (granting to the AEC the authority to regulate the use of nuclear materials to protect health and minimize danger to life or property); 42 U.S.C. § 5841(f) (1982) (splitting AEC's inconsistent mandate both to promote nuclear utilization and to regulate the safety of nuclear technology; transferring the health and safety regulatory functions to the NRC).

223. It has been suggested that the NRC does not have the statutory authority to use cost-benefit analysis in the development of health standards. *See, e.g.,* Baram, *supra* note 220, at 499. The AEC could reasonably infer that Congress intended economic factors be considered, for the AEC functioned under a dual mandate to both promote and regulate the use of nuclear materials. However, the Energy Reorganization Act of 1974, 42 U.S.C. §§ 5801-5891 (1982), separated those duties and gave the NRC only the regulatory functions. Because the NRC has only the single objective of ensuring health and safety, the 1974 Act arguably limited the NRC's implied authority to weigh economic considerations.

224. Baram, *supra* note 220, at 474; Weinberg, *Benefit-Cost Analysis and the Linear Hypothesis*, 271 NATURE 596 (1978).

225. Baram, *supra* note 220, at 483-86.

sis weakens, on economic grounds, standards whose sole purpose was to protect worker health.

The third conceptual basis for the current occupational exposure limits is the ALARA principle. Although the limits contained in current Standards may be considered permissive, actual exposure in the workplace only rarely will approach the allowed levels if the licensee makes exposures "as-low-as-is-reasonably-achievable" (ALARA). The NRC relies on the ALARA principle to keep exposures below those permitted.²²⁶ The principle was added to replace "the view that an activity was acceptable if the exposures were below a specific limit."²²⁷

The ALARA principle is valuable in its own right, but becomes imperative when considered in conjunction with the linear dose-response assumption and the use of cost-benefit analysis in the formulation of occupational exposure standards. The NRC assumes that health risks from radiation exposure fall along a continuum that increases with dose. By considering economic factors in the formulation of the exposure standards, the NRC necessarily represents the standards as being on the margin, past which generally applicable restrictions on exposure would not return sufficiently valuable health benefits. Within this framework, it is important for the NRC to maintain the ability to require individual licensees to reduce exposure whenever feasible. Given that this flexibility seems necessary for the NRC to fulfill its mandate to protect health and safety, it is disturbing that the NRC currently only recommends, rather than requires, licensees to observe the ALARA principle.

Persons engaged in activities under licenses issued by the Nuclear Regulatory Commission . . . *should* . . . make every reasonable effort to maintain radiation exposures . . . as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.²²⁸

B. *Application in the Occupational Context*

1. *Permissible Doses, Levels, and Concentrations*

The current occupational radiation dose limits²²⁹ relate only to exposure received in the course of employment; a worker's exposure from

226. See 40 Fed. Reg. 799, 800 (1975) (codified in scattered sections of 10 C.F.R. pts. 19 & 20 (1986)) (implementation of ALARA sufficient to make additional limits on exposure of fertile women of minor effect). See generally COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50.

227. 50 Fed. Reg. at 52,002.

228. 10 C.F.R. § 20.1(c) (1986) (emphasis added).

229. *Id.* § 20.101.

medical treatment or other nonoccupational circumstances need not be considered by an employer.²³⁰ Under the current Standards, a person is not to receive an occupational dose in excess of the limits indicated in the following table:

*REM*²³¹ *PER CALENDAR QUARTER*²³²

Whole body, head and trunk, active blood-forming organs, lens of eye, or gonads	1.25 or 3 with lifetime occupational exposure history and within the 5(n-18) dose averaging formula
Hands and forearms, feet and ankles	18.75
Skin of whole body	7.5

Exposure to the tissues listed in the first category of the above table poses the greatest concern from a reproductive health perspective. The quarterly dose limit to these tissues has a variable individual impact depending on the exposure history of each employee.

There are two considerations that serve as the theoretical bases for the variable standard. First, exposure in any one calendar quarter should be kept at a level that precludes statistically observable biological damage or health effects.²³³ Second, given the possibility of damage from long-term exposure over the course of a career, cumulative lifetime exposure should also be limited to prevent statistically observable biological damage or adverse health effects.²³⁴ While both these considerations embody laudable principles, the approach the NRC currently uses to limit individual doses has an impact on employees that is not justified by health concerns and is not consistent with the ALARA principle.

The goal of limiting noncumulative exposures is accomplished by setting a maximum exposure limit of three rem per quarter, which allows a dose of twelve rem per year.²³⁵ This is the maximum dose a licensee can allow a worker to receive, provided the worker's dose history is considered and the accumulated lifetime dose does not exceed an amount

230. *Id.* § 20.102.

231. A rem is a unit of measurement that is used to describe radiation dose. The word is an acronym formed from the phrase "roentgen equivalent man." The unit is a shorthand representation of the calculations necessary to estimate the biological impact of radiation exposure. A rem is a function of the radiation adsorbed dose (rad) and the relative biological effectiveness (RBE) for the particular type of radiation. J. GOFMAN, *supra* note 3, at 47.

232. 10 C.F.R. § 20.101 (1986).

233. 50 Fed. Reg. at 51,996.

234. *Id.*

235. 10 C.F.R. § 20.101(b)(1) (1986).

determined by the formula $5(N-18)$ rem.²³⁶ Three rem per quarter is the most permissive standard and is the one most frequently applied to new and temporary workers.²³⁷

Cumulative lifetime dose is limited by the averaging formula $5(N-18)$, where N is the worker's age at his last birthday.²³⁸ The purpose of this formula is to set an upper limit on cumulative lifetime dose. However, the formula can affect employees differently, depending solely on their ages and not on any health-based rationale. For a permanent employee with a long history of exposure, the formula will become the limiting constraint and will set an exposure limit of 1.25 rem per quarter or five rem per year. But for a new or temporary employee with no prior dose history, the formula will provide the exposure limit only if the em-

236. *Id.* § 20.101(b)(2).

237. In the nuclear industries, the case of "temporary" or "transient" workers has greater significance than is immediately obvious. Temporary workers are hired, exposed, and then dismissed as a means of evading exposure limits. See Franklin, *Atom Plants Are Hiring Stand-Ins to Spare Aides the Radiation Risk*, N.Y. Times, July 16, 1979, at 1, col. 1. Attention was first focused on the issue of temporary workers through congressional investigations of a nuclear reprocessing and waste storage facility that was plagued by design defects and frequent breakdowns that resulted in high occupational exposures. During its six-year history, the company employed about 170 full-time workers, but, in 1971 alone, it used 991 temporary workers. HOUSE COMM. ON GOVERNMENTAL OPERATIONS, WEST VALLEY AND THE NUCLEAR DILEMMA, H.R. REP. NO. 775, 95th Cong., 1st Sess. (1977). Thirty percent of the occupational radiation exposure accrued to temporary workers, each of whom had less than one day's work, yet less than one percent of the plant's total wages went to temporary workers. R. Kates & B. Braine, *The Locus of Benefits and Risks of West Valley Wastes* (undated and unpublished manuscript), quoted in M. Melville, *The Temporary Worker in the Nuclear Power Industry: An Equity Analysis 3* (1981) (unpublished manuscript).

Concern over the use of temporary workers led the NRC to analyze the mandatory reports filed by nuclear power companies. OFFICE OF MANAGEMENT AND PROGRAM ANALYSIS, U.S. NUCLEAR REGULATORY COMM'N, OCCUPATIONAL RADIATION EXPOSURE, TENTH ANNUAL REPORT, 1977 (1978). These reports showed trends that would be expected given the increased use of temporary workers. Between 1973 and 1977, the number of nuclear power workers exposed to measurable amounts of radiation tripled to 71,904. The average level of exposure declined from 0.87 to 0.74 person-rem per year. However, an eightfold increase occurred in the number of transient workers, from 157 to 1,311. The average exposure of these workers fell from 0.89 to 0.52 person-rem per year. M. Melville, *supra*, at 2.

The NRC's estimate of the size of the temporary workforce has been criticized as being a gross underestimate. *Id.* Rather than accept the NRC's narrow definition of "transient workers" as those individuals hired and terminated by two or more employers during a three-month period, an estimate eighteen times greater was derived by defining the class as all workers hired and terminated once by any licensee during any one year. *Id.* Under this definition, there were 23,520 temporary nuclear power workers in 1977, and they represented 35% of the monitored workforce. These workers received approximately 47.5% of the occupational radiation dose. *Id.*

Data concerning the prevalence of temporary workers in other industries involving radiation exposure are not available.

238. M. Melville, *supra* note 237, at 2. The use of the number 18 in the formula apparently derives from the NRC's restriction on exposures to workers under 18 years of age to 0.125 rem per quarter. 10 C.F.R. § 20.102 (b)(1) (1986). It appears the NRC deems such levels of premajority exposure to be negligible and therefore discountable in the calculation of cumulative dose.

ployee is young. If the employee is not relatively young, the quarterly limit of three rem, or twelve rem per year, will serve as the limit on dose.

The disparate impact of this approach can best be demonstrated by example. Assume that two potential employees, one eighteen and one thirty years old, apply for work at a nuclear fuel processing facility. Neither of the applicants admits any prior occupational radiation exposure.²³⁹ A second assumption, and one that requires no leap of faith, is that it is expensive for a licensee to implement work practices or engineering or process controls that reduce worker exposure to radiation.

The licensee is driven by economic realities. Confronted with these two applicants and a nuclear materials license that mandates compliance with the NRC's exposure Standards, the licensee will award the job to the thirty-year-old applicant. For the older applicant, mathematical manipulation of the cumulative dose averaging equation results in a limiting value of sixty rem. Thus, the cumulative dose limit becomes irrelevant and the licensee is able to allow exposure of the thirty year old at the rate of three rem per quarter or twelve rem per year. In fact, the employee can be exposed at a rate of twelve rem per year for the next ten years of employment before the cumulative-dose-averaging equation becomes limiting and restricts the quarterly exposure to 1.25 rem.

In comparison, the licensee could allow exposure of the eighteen-year-old applicant only up to 1.25 rem per quarter by the cumulative dose averaging equation immediately upon the youth's employment. As a result, two job applicants, for whom radiation exposure poses the same health risk, are differentiated solely on the basis of age. Furthermore, if both applicants were hired, the licensee would be required to apply different exposure limits to each worker despite their identical susceptibility to radiation injury.²⁴⁰

There are four important problems with the NRC's current variable dose limit approach to regulating occupational exposure. First, the Standards encourage discrimination on the basis of age. An older employee with no prior exposure history can be exposed to significantly higher occupational radiation levels than a younger employee with no prior exposure history, despite the fact that the risk to each is equivalent. Second, allowing different exposure limits implicitly undermines the recommended ALARA principle. Rather than requiring licensees to achieve workplace radiation levels that are low enough to ensure that no em-

239. Before allowing a new employee to enter an area where radiation is present, the licensee must obtain from the employee a written statement disclosing all prior occupational doses of radiation. 10 C.F.R. §§ 20.102(a), (b) (1986). There is no method by which the employer can readily verify the employee's statements.

240. Thus, by using this method of regulating cumulative dose, the NRC provides an employer with a strong incentive to violate the Age Discrimination in Employment Act of 1967, 29 U.S.C. §§ 621-634 (1982 & Supp. III 1985).

ployee, regardless of length of employment, accumulates unacceptably high lifetime doses, the current Standards encourage employment of workers who can be exposed at a higher level and then be dismissed.²⁴¹

Third, the age-sensitive radiation standard is overinclusive and excessively paternalistic. The only justification for the variable impact approach is to limit cumulative doses derived from long-term employment in a job involving radiation exposure. But, such jobs are often unskilled, and many workers have neither the desire nor the intention to remain in them on a long-term basis. To set exposure limits that are effectively lower for younger workers is tantamount to restricting employment opportunities for those workers. Limiting employment to avoid potential long-term cumulative dose hazards is unduly restrictive of those workers who only contemplate short-term employment. While it is necessary to limit cumulative dose, it should be the worker's prerogative to decide when and at what rate he or she will accumulate that dose.

The fourth criticism concerns transient workers.²⁴² Because the worker controls the employer's knowledge of the worker's prior exposure history, there is a strong motive for each worker to deny previous exposure to convince a licensee that the worker can be exposed at the rate of three rem per quarter. By lying to a series of employers, a worker can accumulate a lifetime dose in excess of that currently deemed safe.²⁴³ If

241. The practice of hiring temporary workers to accomplish jobs that entail high exposure rates and rapid attainment of dose limits is well-documented. See generally M. Melville, *supra* note 237; Gillette, *Transient Nuclear Workers: A Special Case for Standards*, 186 SCIENCE 125 (1974); Franklin, *supra* note 237, at 1.

242. *Id.* See *supra* note 237.

243. The concerns raised by the use of temporary workers are not limited to the problem of overexposing individual workers. The practice also raises fears about increasing the risk of genetic impairment in the overall population as well as the issue of pay equity.

A principal purpose of limiting occupational exposure to radiation should be to minimize genetic risk to the population as a whole. This purpose is manifest in the ALARA principle, which recommends minimizing the genetic risk resulting from necessary occupational exposures. The use of temporary workers obviously circumvents the purpose of the ALARA principle; rather than lowering net exposure, the licensee merely spreads the exposure over a larger workforce. Because genetic injuries are believed to be proportional to dose, a large exposure of a small number of workers can pose the same risk to future generations as small exposure to a large number of workers. J. GOFMAN, *supra* note 3, at 585. The *Bulletin of Atomic Scientists* has expressed this concern:

The fact that many nuclear power plants are finding it necessary to solve the individual exposure problem of repair work in persistently high radiation areas by hiring temporary employees to spread out the dose has increased the overall cancer and genetic risks to the population, which is exactly what we should try to avoid.

Morgan, *Cancer and Low-Level Ionizing Radiation*, 34 BULL. ATOM. SCI. 38 (1978).

The problem of pay equity has been described as follows:

Whether a worker receives his quarterly maximum of 3 rem in three months or in three minutes may make no biological difference. But if, as is generally assumed, every exposure carries some discrete risk of genetic damage or illness, then the full-time worker who earns three months' pay for three months' radiation benefits considerably more than the worker who accepts the same risk—knowingly or not—for half a day's pay.

the NRC set one exposure standard applicable to all workers and low enough to prevent a cumulative exposure hazard, all of these problems would be ameliorated.

The NRC's current Standards require a licensee to determine a new employee's prior dose whenever that employee is likely to receive an occupational exposure in excess of twenty-five percent of the levels specified in the table reproduced above.²⁴⁴ A potential exposure to the gonads of 0.125 rem would trigger the calculation of prior dose history. This calculation depends entirely on information given by the employee.²⁴⁵ The employee must sign a statement that he has had no prior occupational dose during the current calendar quarter or, if he has been exposed during that quarter, he must reveal the nature and amount of radiation received.²⁴⁶ If the licensee plans to permit exposure greater than 1.25 rem in a calendar quarter, he must calculate, on a form provided by the NRC, the previously accumulated occupational dose received by the employee. In this way, the employer can ensure compliance with the 5(N-18) rem cumulative exposure limit.²⁴⁷

The current Standards for Protection Against Radiation limit the exposure of workers under eighteen years of age to a quarterly dose of ten percent of the limits specified in the above table.²⁴⁸ A minor's whole-body or gonadal irradiation cannot exceed 0.125 rem per quarter.²⁴⁹ No explicit reason is given for this reduced dose. The NRC may have selected the number arbitrarily in recognition of the greater radiosensitivity of developing biological systems.

Worker exposure to concentrations of airborne radioactive materials and to radioactive materials through the skin is restricted; internalization by either route in any calendar quarter cannot exceed material-specific limits set forth in appendix B of the Standards for Protection Against Radiation.²⁵⁰ Appendix B contains more restrictive limits for minors.²⁵¹ Further, and consistent with the ALARA recommendation, the licensee is required to use process or engineering controls or to change work patterns, to minimize concentrations of radioactive materials in the air.²⁵²

Gillette, *supra* note 241, at 125. It is not argued here that the NRC should attempt to establish equitable pay levels; that is not its function. An informed worker should be allowed to choose whether to accept employment that carries a risk of radiation injury. J. GOFMAN, *supra* note 3, at 584. However, a worker has a right to know about all employment-related risks, and the NRC should intercede to ensure that this right is protected among temporary workers.

244. 10 C.F.R. § 20.102 (1986).

245. *Id.*

246. *Id.* § 20.102(a).

247. *Id.* § 20.102(b)(1)-(2).

248. *Id.* § 20.104.

249. *Id.*

250. *Id.* pt. 20 app. B.

251. *Id.*; see also *id.* § 20.104(c).

252. *Id.* § 20.103(b)(1).

When it is impracticable to use such controls, other precautionary procedures, including limitation of working time or provision of respiratory protective equipment, are required.²⁵³ Inhalation protection is important because many radioactive materials used in nuclear industries cannot damage reproductive systems unless internalized.

2. *Precautionary Procedures*

There are three main precautionary procedures required of all NRC licensees. First, licensees must make periodic surveys to evaluate the extent of radiation hazards.²⁵⁴ Surveys review and analyze the hazards incident to the presence of radioactive materials and include measurements of radiation levels.²⁵⁵

Second, licensees must supply personnel monitoring equipment and require its use.²⁵⁶ The worker's age determines whether or not he or she must wear a monitor. Any adult likely to receive twenty-five percent, and any minor likely to receive five percent, of the quarterly dose limits specified in the above table must wear a monitor.²⁵⁷

Third, licensees are required to clearly mark restricted areas, i.e. areas controlled for the purpose of protecting workers from exposure.²⁵⁸ The Standards prescribe the design of the warning device. Radioactive containers and access points to radiation areas also must be plainly marked.²⁵⁹

3. *Records, Reports, and Notifications*

All licensees are required to maintain records of radiation surveys and personnel exposure.²⁶⁰ Yearly reports to the NRC concerning employee exposure are required only for licensees in the industries thought to experience the greatest exposure.²⁶¹ These industries include nuclear reactors, radiography, fuel processing, high-level waste repositories, spent fuel storage, and facilities using specified quantities of byproduct material.²⁶² Reports must detail the number of workers monitored and provide a statistical summary of their exposure.²⁶³ This group of licensees must also report to the Commission on the exposure of each worker

253. *Id.* § 20.103(b)(2).

254. *Id.* § 20.201.

255. *Id.*

256. *Id.* § 20.202.

257. *Id.*

258. *Id.* § 20.203.

259. *Id.*

260. *Id.* § 20.401.

261. *Id.* § 20.408.

262. *Id.*

263. *Id.* § 20.407.

after termination of employment.²⁶⁴ All licensees must also report to the NRC any condition that results in overexposure of any worker.²⁶⁵

The regulations also provide for reports to workers and for NRC inspections of facilities.²⁶⁶ Required reports to workers include both general instructions and individual exposure data.²⁶⁷ The general information that must be made available to the workers includes copies of the license, license conditions, operating procedures, and notices of employer violations of radiological working conditions.²⁶⁸ Further, the licensee must instruct employees as to the health protection problems associated with exposure to radioactive materials.²⁶⁹

Licensees must furnish a written report to workers describing their personal radiation exposure data, including an analysis of radioactive materials retained in the body.²⁷⁰ These reports are to be made annually or on termination of the worker.²⁷¹ A former employee can request an exposure report from the employer's records.²⁷²

C. Relevance to Reproductive Risks

Although the current Standards for Protection Against Radiation do not expressly address reproductive health, they do implicitly recognize some of the threats that exposure to radiation poses to a worker's reproductive system. For example, the Standards are designed to limit and minimize exposure of the radiosensitive gonads. A ceiling on lifetime dose also has been established by the 5(N-18) formula to reduce the danger of cumulative doses.²⁷³ An awareness of the increased susceptibility of developing biological systems is reflected in regulatory differentiation on the basis of age: quarterly exposure of an employee under eighteen is restricted to ten percent of that allowed for adults.²⁷⁴

The regulations also reflect the NRC's assumption that there is no sex-linked variation in radiosensitivity. The Standards are uniformly applied to both sexes, including pregnant women. In fact, the NRC prohibits a licensee from discriminating in employment on the basis of sex.²⁷⁵

264. *Id.* § 20.408(b).

265. *Id.* §§ 20.403, 20.405.

266. 10 C.F.R. pt. 19 (1986).

267. *Id.* § 19.1.

268. *Id.* § 19.11.

269. *Id.* § 19.12. In conjunction with the requirement that licensees instruct employees on the general health problems associated with radiation, the NRC, through Regulatory Guide 8.13, suggests information that should be given concerning the biological effects of prenatal exposure to embryos or fetuses. OFFICE OF STANDARDS DEVELOPMENT, *supra* note 217, at 1.

270. 10 C.F.R. § 19.13 (1986).

271. *Id.* § 19.13(a).

272. *Id.* § 19.13(c).

273. 10 C.F.R. § 20.101(b)(2).

274. *Id.* § 20.104.

275. 10 C.F.R. § 19.32.

In short, the NRC's current Standards do account for many of the known reproductive sensitivities to radiation. The limitations on radiation exposure that have been implemented by the Commission represent its determination of acceptable levels of risk for workers.

In sharp contrast to the "implicit judgments" of the NRC on the acceptable level of risk to the reproductive health of male and female radiation workers, prior to its new proposed Standards,²⁷⁶ the Commission had declined to adjust exposure limits to account for the heightened radiosensitivity of the embryo/fetus.²⁷⁷ This policy continued despite the NRC's recognition of the increased susceptibility of developing biological systems,²⁷⁸ and recommendations from scientific councils that exposures of fertile women be reduced to protect the embryo/fetus. Both the International Commission on Radiation Protection (ICRP)²⁷⁹ and the National Council on Radiation Protection and Measurements (NCRP)²⁸⁰ have recommended reduced occupational exposure limits for fertile women who are exposed to radiation on the job.

In 1965, the ICRP recommended the employment of women of reproductive capacity only under conditions where the abdominal dose does not exceed 1.3 rem per quarter—corresponding to five rem per year—and is delivered at an even rate.²⁸¹ The ICRP found that this restriction on all fertile women was necessary due to the radiosensitivity of the embryo during the critical stages of development, which occur early in pregnancy.²⁸² Under these exposure conditions, the ICRP believed that the dose to the embryo normally would not exceed one rem during the critical first two months of organogenesis.²⁸³ Once a pregnancy was

276. 50 Fed. Reg. 51,992 (1985) (to be codified at 10 C.F.R. pt. 20) (proposed Dec. 20, 1985).

277. See *infra* text accompanying notes 289-307.

278. See, e.g., 50 Fed. Reg. at 52,008 ("The susceptibility of the embryo/fetus to damage by radiation is well established and recent information suggests that the period from 10 weeks to 17 weeks in development may be especially critical."); OFFICE OF STANDARDS DEVELOPMENT, *supra* note 217, at 1 ("It follows that children could be expected to be more radiosensitive than adults, fetuses more radiosensitive than children, and embryos even more radiosensitive."); 40 Fed. Reg. 799 (1975) ("An embryo is especially radiosensitive during critical stages of embryogenesis in the early months of pregnancy.")

279. The International Commission of Radiation Protection (ICRP) is a private nonprofit organization comprised of professionals in disciplines related to nuclear energy. Founded in 1928, the ICRP has published recommendations and general guidance on the use of radiation sources since 1950.

280. The National Council on Radiation Protection and Measurements (NCRP) is a nonprofit corporation chartered by Congress in 1964 and comprised of nuclear scientists. The NCRP publishes information and recommendations based on scientific judgments on matters concerning radiation protection and measurement.

281. INTERNATIONAL COMMISSION ON RADIATION PROTECTION, PUB. NO. 9, RECOMMENDATIONS OF THE INT'L COMM'N ON RADIATION PROTECTION 11 (1965); see also 40 Fed. Reg. 799 (1975).

282. INTERNATIONAL COMMISSION ON RADIATION PROTECTION, *supra* note 281, at 11.

283. *Id.*

discovered, the ICRP recommended controlling the mother's exposure so that the dose to the embryo/fetus accumulated during the remaining period of gestation would not exceed one rem.²⁸⁴

In 1971, the NCRP recommended that "[d]uring the entire gestation period, the maximum permissible dose equivalent to the fetus from occupational exposure of the expectant mother should not exceed 0.5 rem."²⁸⁵ To ensure a limited dose to the embryo/fetus, the NCRP also recommended restrictions on the employment of fertile women:

The need to minimize exposure of the embryo and fetus is paramount. It becomes the controlling factor in the occupational exposure of fertile women. In effect, this implies that such women should be employed only in situations where the annual dose accumulation is unlikely to exceed 2 or 3 rem and is acquired at a more or less steady rate. In such cases, the probability of the dose to a fetus exceeding 0.5 rem before a pregnancy is recognized as negligible. Once a pregnancy is known, the actual approximate dose can be reviewed to see if work can be continued within the framework of the limit set above. It should be particularly noted that . . . the dose equivalent should not exceed 0.5 rem. In terms of conventional NCRP usage, the word "should" as used here is less restrictive than the word "shall" that appears in other statements of maximum permissible dose equivalent. The purpose of this is to acknowledge that the method of application (as suggested above) is speculative and needs to be tested for practicality in a wide range of occupational circumstances. For conceptual purposes the chosen dose limit essentially functions to treat the unborn child as a member of the public involuntarily brought into controlled areas. Despite the use of the permissive "should" terminology, the NCRP recommends vigorous efforts to keep exposure of an embryo or fetus to the very lowest practicable level.²⁸⁶

Implementing the recommendations of the ICRP and the NCRP would require a substantial modification of the NRC's existing Standards. Whereas the Commission's current Standards treat male and female workers identically, both the ICRP and NCRP recommend more restrictive radiation exposure limits for all fertile women. Generally, the Commission has proceeded on the assumption that both sexes are equally radiosensitive and, until recently, apparently chose to disregard the increased radiosensitivity of the embryo/fetus in setting its standards. In contrast, the ICRP and the NCRP focused on the heightened radiosensi-

284. *Id.*

285. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, REPORT NO. 39, BASIC RADIATION PROTECTION CRITERIA 92 (1971); *see also* 40 Fed. Reg. 799 (1975).

286. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, *supra* note 285, at 92-93; *see also* 40 Fed. Reg. 799 (1975). The NCRP Board of Directors reaffirmed these recommendations in 1974 after being questioned about their propriety in light of concerns about sex discrimination, invasion of privacy, and the legality of limitations applicable only to fertile women. *See* 40 Fed. Reg. 799 (1975).

tivity of the embryo/fetus, and apparently believed that protection of the fetus was important enough to justify the differential treatment of all fertile women.

The options available to the Commission to implement these suggested revisions in its Standards all involve problematic choices. For example, the Commission could require reduction in the radiation exposure of all workers so the knowing or unknowing exposure of any potential embryo/fetus would be within acceptable levels.²⁸⁷ This approach would be very expensive and might necessitate the employment and exposure of more workers, albeit to lower levels of radiation.²⁸⁸

A second option would be to require reduced exposures of all fertile women to protect any potential embryo/fetus. However, this option would have a disparate impact on women, is on its face overinclusive (since it would affect both pregnant and nonpregnant women), and would have a negative impact on women's employment opportunities in the nuclear industries.

A third option would be to regulate the exposure of women once they are pregnant. This option ignores, however, exposures during the critical embryonic developmental period prior to the discovery of pregnancy. It also would have a disparate impact on pregnant women's employment opportunities.

Faced with such difficult options, the Commission for many years proposed to do little and, until late 1985, did nothing. The NRC did acknowledge the danger to the embryo/fetus and the recommendations of the ICRP and NCRP that exposure of fertile and pregnant women be restricted.²⁸⁹ However, the NRC only proposed that licensees be required to provide additional instructions cautioning workers of the increased risk to the embryo/fetus.²⁹⁰ While purporting to "incorporate the intent of the recommendation of the National Council on Radiation Protection and Measurements . . . that the radiation exposure to an embryo or fetus be minimized,"²⁹¹ the Commission simply suggested the addition of two phrases to its existing regulations.

287. Note that the NCRP and the ICRP differed significantly on the acceptable maximum dose to which an embryo/fetus should be exposed. The ICRP believed that neither an embryo nor a fetus should be exposed to more than one rem. INTERNATIONAL COMMISSION ON RADIATION PROTECTION, *supra* note 281, at 11-12; *see also* 40 Fed. Reg. 799 (1975). In comparison to this gestational dose limit of approximately 2 rem, the NCRP recommended that the gestational dose not exceed 0.5 rem. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, *supra* note 285, at 92.

288. *See* 40 Fed. Reg. 799 (1975); *see also infra* text accompanying note 295.

289. "At the same time, the Commission considers that the evidence of greater radiosensitivity of the embryo and fetus, and the concern expressed by both the ICRP and the NCRP over the possible adverse effects on the human embryo and fetus, should be taken into account." 40 Fed. Reg. at 800.

290. *Id.*

291. *Id.* at 799.

Section 19.12 of the NRC's regulations, entitled "Instructions to Workers,"²⁹² was to be expanded to include the phrase "including biological risks to embryos or fetuses" as an additional mandatory subject of instructions to be given to employees by licensees.²⁹³ A second phrase, "[s]uch persons should make particular efforts to keep the radiation exposure of an embryo or fetus to the very lowest practicable level during the entire gestation period as recommended by the National Council on Radiation Protection and Measurement," was to be added to the precautionary language of the ALARA principle.²⁹⁴

The Commission did not propose that the dose-limiting sections of the Standards be changed. The NRC did marshal several arguments to justify its failure to modify the occupational exposure limits and counter the council's view that revision of the dose limits were of paramount importance. In essence, the Commission did not believe that a reduction of exposure limits was practicable or necessary. In rejecting the option of reducing dose limits applicable to all workers, the Commission found that:

Reduction of the dose limits for all radiation workers in order to avoid discrimination against women does not appear practicable. Such a reduction in the dose limits would cost the nuclear industry large sums of money in the application of design and engineering changes and in some cases, the employment of additional workers in order to accomplish essential work within the reduced individual dose limits. The latter could even result in a net increase in total man-rem of exposure. Reduction of the dose limit for all workers would aggravate an existing shortage of available manpower in certain key occupations, e.g., radiographers, welders, and pipefitters, that may involve a relatively high radiation exposures.²⁹⁵

The Commission also rejected as unnecessary and discriminatory the option of establishing lower exposure limits for fertile women.²⁹⁶ The Commission argued that:

In evaluating the potential risk to fetuses, one should take into account the fact that women are less than proportionately represented in those occupations most likely to involve relatively high occupational exposures. Also, many women, for one reason or another, are not fertile; and, at any given time, only a small portion of the fertile women being exposed are pregnant.²⁹⁷

292. 10 C.F.R. § 19.12 (1986).

293. 40 Fed. Reg. at 800. The current language of 10 C.F.R. § 19.12 remains the same today as when the proposed revision was published in 1975. 10 C.F.R. § 19.12 (1986).

294. 40 Fed. Reg. at 800. The ALARA principle is embodied in 10 C.F.R. § 20.1 and remains substantively the same today as it was when the proposed revision was published in 1975. 10 C.F.R. § 20.1 (1986).

295. 40 Fed. Reg. at 799.

296. *Id.*

297. *Id.*

Further, the Commission believed that the "continued implementation of ALARA in its licensing and enforcement process and in its operations will result in further reduction in radiation doses, and may make specific adoption of the NCRP recommendation regarding additional limitation on exposure of fertile women of minor effect."²⁹⁸ The potential impact of the ICRP's and NCRP's recommendations on women's privacy and employment opportunities also dissuaded the Commission from revising the dose-limiting Standards.²⁹⁹

The Commission's unwillingness to revise the dose-limits applicable to fertile women does have some merit. Regulations that have a disparate impact on one sex must be justified by a compelling purpose. The Commission cogently argued that the magnitude of the threat to the embryo/fetus was insufficient to support standards that discriminate against either fertile or pregnant women workers.

However, the Commission also failed to adopt the proposed changes in the language of sections 19.12 and 20.1.³⁰⁰ The Commission had recognized the need to account for the danger posed to the embryo/fetus in proposing mandatory instructions to workers and the application of the ALARA principle to insure reproductive health.³⁰¹ None of the Commission's arguments against sexually disparate exposure standards were directed at the changes contained in the proposed additional language. In fact, the required instructions to workers and the recommended application of the ALARA principle³⁰² would seem to be the least intrusive means of addressing the recognized need to protect the embryo/fetus.

Against this background, it is difficult to understand the Commission's failure to adopt the proposed language. However, this decision did not result in complete inaction. Although the proposal to expand the ALARA principle to include embryonic and fetal health was not adopted, the proposal to require instructions was issued as an appendix to Regulatory Guide 8.13 entitled "Instructions Concerning Prenatal Radiation Exposure."³⁰³ The Guide encourages licensees to instruct all workers about the biological risks to embryos and fetuses arising from radiation exposure, and of the need for women to minimize exposures when pregnant.³⁰⁴

In sum, until 1985, the NRC rejected the recommendations of the ICRP and NCRP although it recognized the substantive scientific basis for those recommendations; the Commission refused to amend its Stan-

298. *Id.* at 800.

299. *Id.*

300. *See supra* text accompanying notes 292-94.

301. *See supra* note 289.

302. Under the current standards, the implementation of the ALARA principle is not mandatory. *See supra* text accompanying note 228.

303. OFFICE OF STANDARDS DEVELOPMENT, *supra* note 217.

304. *Id.*

dards to differentiate fertile or pregnant women; licensees were not required to implement the ALARA principle to specifically protect the embryo/fetus; and licensees were not required to give special instructions to workers concerning the danger to the embryo/fetus. However, the Commission encouraged licensees, by a nonbinding regulatory guide, to provide instructions to workers to protect the unborn. This result was an inadequate response to the need to protect the embryo/fetus from radiation exposure.

A final feature of the current Standards for Protection Against Radiation that threatens the health of the embryo/fetus is its failure to control the rate of radiation exposure. While the Standards place a maximum limit on a worker's dose per quarter, they do not prevent that limit from being attained in a very short time period. It does not appear that the rate of exposure increases the risk for adult workers: three rem carry the same probability of genetic damage whether attained in minutes or in weeks.³⁰⁵ However, the failure to restrict the rate of exposure does threaten fetal health. A focused exposure that coincides with a sensitive stage of embryonic or fetal development can have severe health effects.³⁰⁶ While a pregnant woman's exposure may be well within the quarterly dose limit, the current Standards do not prevent this exposure from being attained in seconds.³⁰⁷

IV

PROPOSED REVISIONS TO NRC'S STANDARDS

On December 20, 1985, the NRC proposed revisions to the current Standards for Protection Against Radiation.³⁰⁸ The proposed changes are a positive development in radiological health protection. The fundamental change in the proposed Standards is the articulation of a clear, health-based rationale for the new exposure limits.

The proposed Standards redefine current occupational exposure limits to reduce present exposures and improve the uniform application of the limits to all workers.³⁰⁹ In view of the nonthreshold, dose-response nature of radiation injury, any reduction of exposure levels results in general health benefits, including reduced risk of reproductive injury. The proposed revision also specifically recognizes the radiosensitivity of the embryo/fetus and requires significant limitations on the exposure of pregnant women. While the proposal is not a solution for all the

305. See J. GOFMAN, *supra* note 3, at 48-49.

306. See *supra* text accompanying notes 85-96.

307. Both the NCRP and the ICRP recognized this problem and suggested that fertile women should only be employed under conditions where exposure is at an even rate. 40 Fed. Reg. 799 (1975).

308. 50 Fed. Reg. 51,992 (1985).

309. *Id.* at 52,008-09.

problems incident to occupational exposure to radiation, the proposed Standards do indicate that the NRC has responded to the criticisms outlined above.

The proposed Standards replace the NRC's "implicit judgments on health effects"³¹⁰ with explicit estimates of health risk. The NRC's proposal is a "recognition of the extensive knowledge concerning the probability of suffering radiation-induced health damage and the merit of using this knowledge to form a rationale for standards."³¹¹ In the proposal, limits on occupational exposure are determined by a two-step process. First, the risk of the occurrence of radiation-induced random health effects, e.g., cancer or hereditary disease, is quantified for different exposure levels.³¹² In a second discrete step, judgments are made concerning the acceptability of the risk associated with different exposure levels.³¹³ When an appropriate level of risk has been determined, occupation exposure limits are set accordingly.³¹⁴ The proposed limits are set so that the "acceptable" level of risk is a one in ten thousand chance per year that a worker will develop a fatal cancer or a serious hereditary disorder.³¹⁵

Based on this risk level, new limits were developed, and they are reproduced in the following table. The current limits are also provided for comparison.

This approach to standard-setting is based on the solid principle that exposure limits intended to protect health should be based on a clear, health-risk rationale.³¹⁶ Reliance on this rationale will force a shift in the weight given to each of the three conceptual bases that underlie the current Standards—the linear dose-response assumption, the ALARA principle, and cost-benefit analysis³¹⁷—and will increase occupational

310. *Id.* at 51,992.

311. *Id.* at 51,993.

312. *Id.* at 51,992.

313. *Id.* at 51,992-93.

314. *Id.* at 51,993.

315. *Id.* at 51,996.

316. A secondary benefit of this two-step standard-setting process is that it may be more amenable to judicial review than the previous procedures. Many of the NRC's current activities are so technical that courts recognize their lack of competence to review effectively the Commission's decisions. The courts thus tend to defer to the Commission's administrative expertise. *See, e.g.,* Crowther v. Seaborg, 312 F. Supp. 1205, 1220 (D. Colo. 1970) *aff'd*, 415 F.2d 437 (10th Cir. 1969) (all that is required to establish the reasonableness of the NRC's exposure standard is that it be made carefully in light of the best of available scientific knowledge); Baltimore Gas and Elec. Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 103 (1983) (court must be most deferential when the NRC makes predictions, within its area of special expertise, at the frontiers of science). By dividing the standard-setting process into a scientific step, i.e., the estimation of risk, and a sociopolitical step, i.e., the determination of the acceptability of risk, the NRC may be exposing itself to greater judicial review. At least at the second step, judgments about the acceptability of risk do not appear to be within the NRC's special expertise.

317. *See supra* text accompanying notes 217-28.

TABLE TWO
CURRENT AND PROPOSED OCCUPATIONAL EXPOSURE STANDARDS†

<u>CURRENT STANDARDS</u>		<u>PROPOSED STANDARDS</u>	
Whole body, head and trunk, active blood-forming organs, lens of eye, or gonads	1.25 or 3 rem††/quarter (5 or 12 rem/year) with lifetime occupational exposure history and within the 5(N-18) dose averaging formula	Whole body, head, trunk, arm above elbow, leg above knee, and gonads	3 rem/quarter, not to exceed 5 rem/year
Hands and forearms, feet and ankles	18.75 rem/quarter (75 rem/year)	Lens of eye	15 rem/year
Skin of whole body	7.5 rem/quarter (30 rem/year)	Hand, elbow, arm below elbow, foot, knee, and leg below knee	50 rem/year
ALARA	Recommended	Skin of whole body	50 rem/year
Embryo/fetus	Not addressed	ALARA	Required
		Embryo/fetus	0.5 rem during entire gestation

† 50 Fed. Reg. 51,994-96 (1985).

†† See *supra* note 231.

radiation safety.

The linear dose-response assumption is retained by the proposed Standards: “[i]ntrinsic in the assumption of a direct proportionality between dose and health damage is the presumption that radiation-induced health damage can occur at any non-zero value of dose”³¹⁸ This assumption plays a central role in fostering an overall regulatory perspective that exposures must be kept low.

Moreover, the proposed Standards recognize the crucial role the ALARA principle must play in reducing radiation exposures. The revision would require, rather than merely encourage, all licensees to incorporate ALARA provisions into their radiation protection programs.³¹⁹ This change in the language of the ALARA principle from precatory to mandatory would be an important step towards minimizing exposure to radiation.³²⁰

The most beneficial change that would result from the implementation of the proposed Standards would be a limitation of the use of cost-benefit analysis.³²¹ In a standard-setting process that first quantifies risk and then judges the acceptability of that risk by comparing it to other nonradioactive industries, it is not clear where cost-benefit analysis would be used. Economic considerations would not be factors in the estimate of risk, for these estimates only involve the scientific quantification of the probability of occurrence of negative health consequences at various exposure levels.

If cost-benefit analysis were used at all in the proposed method of establishing standards, it would be restricted to phase-two judgments concerning the acceptability of risk. Even if used in this capacity, economic considerations would be offset by explicit health benefits and would therefore carry less weight.³²² Ideally, economic factors would not be considered at all in the proposed method of establishing radiation health standards, but would be important only in determining the most cost-effective means of maintaining those standards.³²³

The NRC’s proposed health-risk based Standards would require a

318. 50 Fed. Reg. at 52,001.

319. *Id.* at 52,002. The proposed ALARA language reads:

(a) Each licensee shall ensure that the dose to individuals receiving occupational doses and to members of the public is as low as is reasonably achievable (ALARA) and does not exceed the appropriate limits. Procedures and engineering controls based on sound radiation protection principles should be used, to the extent practical, to reduce potential exposures.

(1) Each licensee shall develop and implement a radiation protection program including provisions for keeping dose equivalents ALARA.

Id. at 52,029.

320. *See supra* text accompanying notes 226-28.

321. *See supra* text accompanying notes 220-25.

322. *Id.*

323. For a discussion of the distinction between cost-benefit and cost-effective analyses, see Baram, *supra* note 220, at 473.

reduction in the exposure of the general workforce to radiation. While the three-rem-per-quarter limit would be retained, annual exposures would be restricted to five rem.³²⁴ This five-rem limit would be a significant reduction from the current permissible annual exposure limit of twelve rem.

The proposed revision also rescinds the 5(N-18) cumulative dose averaging formula. Instead, the proposal suggests procedures for "Planned Special Exposures."³²⁵ These procedures are the only method by which a licensee can allow exposures to exceed the annual five-rem limit. After following restrictive preparatory procedures, a licensee could allow a worker to receive up to ten rem per year.³²⁶ To limit cumulative doses, a worker could not be exposed under the Planned Special Exposure procedures more than five times in his or her lifetime.³²⁷ This limits to twenty-five rem the allowable exposure in excess of that accumulated at five rem per year. In general application, this approach restricts cumulative doses much more than the current 5(N-18) formula. To further ensure that annual exposures are kept at five rem, the availability of the Planned Special Exposure procedures is conditional.³²⁸

The proposed approach to limiting occupational exposures successfully addresses many of the deficiencies of the current Standards. Because radiation is not thought to have a safe threshold exposure, any exposure will entail a proportionate health risk. By lowering the annual exposure limit from twelve to five rem, the NRC's proposed Standards would significantly reduce health risks. The allowance of three-rem-per-quarter exposure is apparently retained to allow the licensee flexibility in managing exposure while attaining the five rem annual limit.³²⁹

The elimination of the 5(N-18) cumulative dose-limiting equation is also a positive change. By lowering the annual exposure limit and restricting both the number and magnitude of exposures above that limit, the NRC proposal would lower significantly allowable cumulative doses.

324. 50 Fed. Reg. at 52,003, 52,029.

325. *Id.* at 52,009.

326. *Id.* at 52,009, 52,031.

327. *Id.*

328. A number of limitations would be imposed on licensees prior to use of the planned special exposure provision. A licensee would be required: To ascertain the dose equivalent from all previous planned special exposures and overexposures for all individuals involved; to inform the individuals involved of the purpose of the planned special exposure, the estimated doses and special radiation or other conditions that might be involved in performing the task; to provide instructions in measures to be taken to keep the radiation dose and other risks ALARA; and to provide employees a written report of the radiation dose actually received. These limitations are designed to ensure protection of the workers and to discourage unwarranted use of this provision.

Id. at 52,009.

329. For a discussion of the effect of retaining the three rem quarterly limit on the temporary worker problem, see *infra* note 333.

In addition to lowering cumulative doses, the proposed Standards also assure uniform application of the standards to all workers. By generally removing the worker's age as a criterion in the determination of the applicable limit, the NRC also has removed any incentive in the Standards for a licensee to discriminate in employment on the basis of age.³³⁰

Further, the licensee would not be able to hire older workers with higher permissible exposure limits to circumvent the ALARA principle.³³¹ Before allowing a planned special exposure that would exceed the five rem annual limit, the licensee would be required to implement the mandatory ALARA principle.³³² By limiting the cumulative dose on an age-neutral basis, the NRC's proposal would also minimize regulatory paternalism. Any worker, regardless of age, would be allowed only five exceptions to the annual limit under planned special exposures during his or her lifetime. When these twenty-five rem would be absorbed would be a decision left to the licensee and the worker.

From both a general and a reproductive health perspective, the NRC's proposed revision of the Standards for the Protection Against Radiation are an encouraging development. By predicating the proposed Standards on health-risk estimates, the NRC would restrict the role of economics in the development of health standards while making the important ALARA principle mandatory. The NRC would also reduce both annual and cumulative exposures, with concomitant health benefits. Moreover, these reductions are accomplished through standards that are uniformly applied and do not encourage employment discrimination on the basis of age. A lingering weakness in the proposed Standards is the NRC's failure to address the problem of the temporary worker, for whom the Commission is content to maintain the status quo.³³³

330. See *supra* text accompanying notes 239-40.

331. See *supra* text accompanying notes 240-41.

332. 50 Fed. Reg. at 52,009, 52,031; see *supra* note 328.

333. By the NRC's own admission, the situation of temporary and transient workers is not improved by the proposed standards:

The 3-rem . . . limit for any calendar quarter is retained . . . to further ensure that short-term workers, transient workers or workers who are rotated between fossil and nuclear facilities will be afforded no less protection under the proposed revision than is provided by the present Part 20.

50 Fed. Reg. at 52,004.

The temporary or transient worker problem is admittedly an intractable one. Regardless of the quarterly dose limit, a worker who chooses not to accurately inform subsequent licensees of his or her exposure history can obtain employment that entails exposures exceeding both the quarterly and annual limits. Nevertheless, the NRC could have proposed reducing these exposures. Even if a radiation worker was not candid in reporting prior exposures, a dose limit below three rem per quarter would effectively reduce that worker's exposure. Given the proposed five rem annual limit, a quarterly limit of 1.25 rem seems appropriate. This limit would significantly reduce exposures of the temporary and transient workforce and would encourage uniformity in exposure rates.

It is not clear why the NRC chose to retain the three rem quarterly limit. The NRC suggests that "[q]uarterly limits allow for earlier identification of occupational overexposures

In addition to these positive steps, the NRC also proposes to address the problem of embryo/fetal radiosensitivity by limiting the exposure of the pregnant radiation worker. The NRC has proposed severely restricted exposure limits for the pregnant radiation worker to protect the embryo/fetus:

The revision of part 20 would require the licensee, following the voluntary declaration of pregnancy by the employee, to limit to 0.5 rem . . . the dose to an embryo/fetus from occupational exposure of the declared pregnant woman throughout the period of pregnancy unless, as noted below, the embryo/fetus may have already received a dose in excess of the limit prior to the declaration.

. . . .

The Commission would not consider the licensee in violation of the proposed revision for exceeding the 0.5 rem dose limit if the embryo/fetus had received 0.5 rem, or more, before the pregnant woman notified the licensee of her pregnancy. In order to permit continued employment of the pregnant woman during the remainder of the pregnancy, and recognizing that it is not possible to avoid some additional exposure in a nuclear facility, the proposed revision would permit an additional one percent of the annual dose limit for workers, e.g., 0.05 rem, to be received by the embryo/fetus during the remainder of the pregnancy.³³⁴

While this language does address concerns regarding the radiological threat to the embryo/fetus, it also portends a serious impact on women's equal employment opportunities in industries involving radiation exposure.

and subsequent earlier investigation into and correction of the causes of such exposures." *Id.* But this truism does not suggest that a particular level of quarterly limit is indicated, only that having some quarterly limit is advisable. The statement applies equally well to a limit of 1.25 rem.

The NRC also suggests that "the dose records do not support a demonstrated need for exceeding 3 rem per quarter, particularly when planned special exposure provisions are available." *Id.* An NRC policy of allowing a licensee some flexibility in managing exposures within the five rem annual limit before the licensee must rely on the Planned Special Exposure procedures seems implicit in this suggestion. But, considering both the size of the temporary and transient workforce and the magnitude of its percentage of the total occupational exposure, see *supra* notes 237-39, the NRC should have proposed a quarterly dose of 1.25 rem and asked licensees to rely on the Planned Special Exposure provisions for managerial flexibility.

334. The proposed regulatory language follows:

(a) Except as noted in paragraph (c) of this section, a licensee shall ensure that the effective dose equivalent to an embryo/fetus due to occupational exposure of a declared pregnant women [sic] does not exceed 0.5 rem . . . during the entire pregnancy. Efforts should be made to avoid substantial variation above a uniform monthly exposure rate which would satisfy this limit.

. . . .

(c) Notwithstanding the limit in paragraph (a) of this section, if the dose to the embryo/fetus is found to have exceeded 0.5 rem . . . by the time the woman declares to the licensee the pregnancy and the estimated date of conception, the licensee is in compliance with paragraph (a) of this section if the licensee does not assign the woman tasks which result in the embryo/fetus receiving an additional dose exceeding 0.05 . . . rem during the remainder of the pregnancy.

From a reproductive health perspective, the NRC's proposed limitation on the exposure of pregnant women is commendable. The radiosensitivity of the embryo/fetus has long been recognized,³³⁵ yet no regulatory action has been taken. In essence, the proposed language incorporates the 1971 NCRP recommendation,³³⁶ although the NRC would only recommend, rather than require, uniform rates of exposure.³³⁷ In its original response to the NCRP recommendation, the NRC recognized the radiosensitivity of the embryo/fetus,³³⁸ and considered a mandatory reduction in the exposures of pregnant women,³³⁹ but ultimately rejected that proposal, arguing that reduced dose limits for pregnant women were not necessary.³⁴⁰

In its proposed revision, the NRC does not counter its previous arguments or suggest why more restrictive limitations on the exposure of pregnant workers have now become necessary. It can be inferred that the change in the NRC's position results from its adoption of a health-risk rationale to support its exposure standards. The quantification of "acceptable" risk under this rationale has led the NRC to propose lower annual and cumulative exposure limits for adults. Although the NRC does not quantify "acceptable" risk for embryos or fetuses, its adoption of a health-risk rationale apparently now leads the Commission to believe lower exposure limits for pregnant women are necessary.

In proposing more restrictive exposure standards for pregnant radiation workers, the NRC has attempted to minimize the negative impact of the Standards on women's employment opportunities. This effort is most evident in the NRC's refusal to propose lower exposure limits for all fertile women:³⁴¹

In order to protect an embryo/fetus before a woman is aware of her pregnancy, a lower dose limit for all fertile women might appear to be desirable. However, establishment of a lower dose limit for all fertile women would result in undue restriction when there is no embryo/fetus to protect and could, therefore, restrict the employment of virtually all women in the nuclear workforce.³⁴²

In an effort to protect a woman's privacy, the NRC's proposal would require the licensee to restrict exposure of the pregnant worker only after she has voluntarily declared herself to be pregnant.³⁴³ Instruc-

335. See *supra* notes 278 & 289.

336. See *supra* text accompanying notes 285-86.

337. See *supra* note 334.

338. See *supra* notes 278 & 289.

339. See *supra* text accompanying note 289.

340. See *supra* text accompanying notes 296-97.

341. Restrictive standards applicable to all fertile women were recommended by both the NCRP and the ICRP. See *supra* text accompanying notes 278-89.

342. 50 Fed. Reg. at 52,009.

343. *Id.*

tions to female workers concerning the risk to the embryo/fetus³⁴⁴ and the woman's interest in the health of her baby would hopefully motivate early detection and acknowledgment of pregnancies. This approach should minimize a licensee's intrusion into a matter as private as a woman's reproductive status.

In an attempt to soften the impact of the proposed lower limit on a woman's ability to remain on the job, the NRC would allow the embryo/fetus to receive an additional 0.05 rem during the remaining period of gestation if an exposure exceeding the 0.5 rem limit had occurred prior to declaration of the pregnancy.³⁴⁵ The NRC would also recommend "that conformance to [the pregnancy exposure] limitation should be achieved without economic penalty or loss of job opportunity and security to workers."³⁴⁶

If reproductive concerns alone are considered, the NRC's proposed limits on the exposure of pregnant women appear commendable. But the proposed Standards concern much more than reproductive health issues. Any differential restriction on the exposure of pregnant women will necessarily undermine the important societal goal of ensuring equal employment opportunity regardless of sex. Although the NRC has attempted to minimize the impact of its proposal on the employment status of pregnant women, it is questionable how successful these efforts would be. Any standard that has a disparate impact on pregnant women can be expected to restrict their job opportunities. Such a policy would also provide unintended support for corporate efforts to exclude all fertile women from job sites involving exposure to fetotoxins.³⁴⁷ Endorsement of the NRC's proposal solely on the basis of reproductive health concerns is inappropriate without first considering the conflict between the Standards and employment discrimination law.

V

TITLE VII AND THE NRC'S PROPOSED STANDARDS

The NRC's proposal to differentiate pregnant women from the rest of the workforce raises a fundamental conflict between two important societal goals. Society has a strong interest in the health of its citizens.

344. See 10 C.F.R. § 19.12 (1986); OFFICE OF STANDARDS DEVELOPMENT, *supra* note 217.

345. 50 Fed. Reg. at 52,009.

346. *Id.*

347. Corporate efforts to exclude fertile and pregnant women from employment are extensive, but are rarely expressed as formal company policies. The premise of these efforts, and the subsequent potential for liability, is that the vulnerability of the embryo during the period prior to detection of the pregnancy is sufficient to warrant exclusion of all fertile women. See *Wright v. Olin Corp.*, 697 F.2d 1172, 1190-91 (4th Cir. 1982); Williams, *Firing the Woman to Protect the Fetus: The Reconciliation of Fetal Protection with Employment Opportunity Goals under Title VII*, 69 GEO. L.J. 641, 644 (1981).

This interest underlies all governmental regulation of health and safety and is manifested in the NRC's proposal to restrict the occupational exposure of pregnant women.³⁴⁸ Society also has a compelling interest in ensuring equal employment opportunities for all its members. A major asset of any society is its diversity. Government or private action that restricts the access of any group, no matter how small or narrowly delimited, to employment opportunities results in a loss to society of incalculable human potential. When the restricted group constitutes a majority of the population, as women do, the societal loss is intolerable.³⁴⁹

Society's interest in equal employment opportunities is codified in Title VII of the Civil Rights Act of 1964³⁵⁰ as amended by the Pregnancy Discrimination Act of 1978.³⁵¹ Title VII forbids discrimination on the basis of sex, and the Pregnancy Discrimination Act explicitly amends Title VII to include discrimination on the basis of pregnancy:

The terms 'because of sex' or 'on the basis of sex' include, but are not limited to, because of or on the basis of pregnancy, childbirth, or related medical conditions; and women affected by pregnancy, childbirth, or related medical conditions shall be treated the same for all employment-related purposes, including receipt of benefits under fringe benefit programs, as other persons not so affected but similar in their ability or inability to work³⁵²

The NRC's proposal to treat pregnant workers differently squarely contradicts the egalitarian command of Title VII.

The magnitude of the Commission's proposals' conflict with Title VII is not mitigated by the NRC's efforts to minimize the impact of the exposure limitations on pregnant radiation workers.³⁵³ Low estimates of the numbers of pregnant radiation workers also cannot reasonably be used to downplay the issue.³⁵⁴ Regardless of the effect on the nuclear

348. Admittedly, the NRC is acting to protect the health of the unborn and not the health of "citizens." However, decisions such as *Roe v. Wade*, 410 U.S. 113 (1973) (a woman's right to privacy limits governmental power to protect the potentiality of life), should not be read to serve as a barrier to government efforts to protect prenatal health. If a woman exercises her right to abort an embryo or fetus, she obviously would no longer be subject to the differential exposure standards proposed for pregnant women. If a woman chooses pregnancy, however, it is to be hoped that she would be subject to occupational exposure standards that are necessary to protect the health of both existing and future generations.

349. "The historical reduction of women's role in life to a single dimension—vessel and nurturer for the next generation—resulted in the sacrifice of tremendous human diversity of talent, predilection, and personal aspiration." Williams, *supra* note 347, at 653.

350. 42 U.S.C. § 2000 (1982 & Supp. III 1985).

351. Pub. L. No. 95-555, 92 Stat. 2076 (1978) (amending Title VII of the Civil Rights Act of 1964).

352. *Id.*

353. See *supra* text accompanying notes 341-46.

354. In the NRC's 1975 decision not to propose restrictive exposure standards for pregnant workers, it minimized the risk by arguing that the pregnant working population was small:

In evaluating the potential risk to fetuses, one should take into account the fact that

industries, which could be substantial for both pregnant and fertile women, adoption of the NRC's pregnancy exposure limits may have a wide-ranging impact on employment opportunities for women in countless other industries.

Although occupational exposure to radiation seems to conjure up the greatest popular fears, the dangers to embryo/fetal health that result from other occupational exposures are also of major significance.³⁵⁵ A large number of reproductive toxicants are used in industry: Rough estimates indicate that as many as twenty million jobs may involve exposure to reproductive hazards.³⁵⁶ OSHA estimates that its standards for exposure to lead alone affect approximately 835,000 men and women in 120 occupations.³⁵⁷

The magnitude of the problem of workplace reproductive hazards heightens the importance of the NRC's proposed differential standards for pregnant workers. In 1979, it was estimated that "at least 100,000 jobs involving contacts with potential teratogens are now closed to women, either because of corporate policies or through subtle channeling of women away from those positions."³⁵⁸ The NRC's proposed approach to the regulation of occupational reproductive health sets a major precedent that may have a significant impact on the employment opportunities available to millions of women.

Because equal employment opportunities are an important societal value, and actions taken in the name of reproductive health could cost society dearly in terms of lost human resources, every effort should be made to remove reproductive health threats from the workplace before Title VII protections are displaced. Pregnant workers who are exposed to reproductive health hazards on the job should not be treated differently unless: (1) sufficient scientific evidence demonstrates that a toxicant poses a significantly greater health risk to the embryo/fetus from direct exposure than from preconception parental exposure; (2) that it is

women are less than proportionately represented in those occupations most likely to involve relatively high occupational exposures. Also, many women, for one reason or another, are not fertile; and, at any given time, only a small portion of the fertile women being exposed are pregnant.

40 Fed. Reg. 799 (1975).

355. See Furnish, *Prenatal Exposure to Fetally Toxic Work Environments: The Dilemma of the 1978 Pregnancy Amendment to Title VII of the Civil Rights Act of 1964*, 66 IOWA L. REV. 63, app. at 119 (1980); AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES ON PREGNANCY AND WORK 23-28 (1977) (listing the many biological, chemical, and environmental occupational exposures that threaten reproductive health); OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 65, at 67-126 (1985) (discussing evidence of chemical, physical, psychological, and biological workplace hazards to reproductive functions).

356. Equal Employment Opportunity Comm'n, *Interpretive Guidelines on Employment Discrimination and Reproductive Hazards*, 45 Fed. Reg. 7514 (1980), *withdrawn*, 46 Fed. Reg. 3916 (1981).

357. OSHA News, 6 JOB SAFETY & HEALTH 2 (1978).

358. Wash. Post, Nov. 3, 1979, § A, at 6, col. 5.

not feasible to lower all exposures to a level where the risk from direct exposures of the embryo/fetus is acceptable;³⁵⁹ and (3) an employer's or a regulatory reproductive health program is narrowly tailored to affect only those employees who are, or who intend to become, pregnant.³⁶⁰ The NRC's proposed response to the reproductive health threat posed by occupational radiation exposure meets these three tests.

Radiation poses a significantly greater risk to reproductive health through direct exposure of the embryo/fetus than through preconception exposure of either the male or the female parent.³⁶¹ The NRC's proposal to lower exposure limits for pregnant women is tolerable only if this differential risk exists.³⁶² The Commission's position on the differential risk draws support from the scientific literature³⁶³ and from the recommendations of two scientific councils.³⁶⁴

The NRC has recognized that radiation can damage reproductive

359. Even if it were feasible to lower exposures sufficiently, the allocation of responsibility for the remaining risk to the unborn would still be a problem. While society and a woman employee may deem the risk "acceptable," an unwilling employer would still be forced to bear the potential moral and economic liabilities that may result from placing the embryo/fetus at risk.

360. See Comment, *Fetal Protection Programs Under Title VII—Rebutting the Procreation Presumption*, 46 U. PITT. L. REV. 755, 792 (1985) (arguing that programs must be narrowly tailored to disallow "demeaning stereotypes concerning reproductive irresponsibility of women"). Exclusion of all fertile women should not be accepted as a sufficiently narrow definition of the class of workers who may be pregnant.

361. See *supra* text accompanying notes 82-96; see also COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATIONS, *supra* note 50, at 492 (after reviewing the primary scientific literature, including that from Hiroshima and Nagasaki, the Committee concludes that "developing mammals, including man, are particularly sensitive to radiation during their intrauterine and early postnatal life"); BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERV., *EFFECTS OF IONIZING RADIATION ON THE DEVELOPING EMBRYO AND FETUS: A REVIEW* 70 (1981). After reviewing human evidence, much of which comes from the therapeutic use of radiation on pregnant women, e.g., X-rays, the study concludes that

the developing embryo and fetus are entities highly sensitive to radiation as well as other chemical, physical and viral agents. This sensitivity varies throughout development and the type and frequency of these effects observed after exposure to these agents are dependent upon the specific state of development and differentiation of the organism when the exposure occurred. It is also dependent on the dose, dose rate, and [relative biological effectiveness] of the radiation.

Id.

The hypersusceptibility of the embryo/fetus to toxins other than radiation is reviewed in Nothstein & Ayres, *Sex Based Consideration of Differentiation in the Workplace: Exploring the Biomedical Interface Between OSHA and Title VII*, 26 VILL. L. REV. 239 (1981). See also Comment, *supra* note 360; Note, *Getting Beyond Discrimination: A Regulatory Solution to the Problem of Fetal Hazards in the Workplace*, 95 YALE L.J. 577 (1986).

362. This point was contained in the proposed EEOC-Department of Labor response to the exclusion of fertile women from the workplace. Equal Employment Opportunity Comm'n, *supra* note 356. One consideration in determining the propriety of an exclusionary policy was to be whether "the hazard is significantly greater for or confined to the class excluded than for the class not excluded." *Id.* at 7516.

363. See *supra* note 361.

364. See *supra* text accompanying notes 278-86.

health prior to conception through both paternally and maternally mediated mechanisms.³⁶⁵ Radiation can cause mutations in the genetic material contained in the sperm or the egg. As there does not appear to be any sex-linked difference in radiosensitivity to germ cell mutations,³⁶⁶ the NRC has proposed dose limits applicable to both sexes so that the risk of a "radiation induced . . . serious hereditary disorder" does not exceed one in ten thousand per year.³⁶⁷ It is the increased risk to the embryo/fetus that results from direct exposure to radiation that has passed through the mother rather than from a parentally mediated pathway that has prompted the NRC to propose lower exposure standards for pregnant women only.³⁶⁸

Technological controls cannot feasibly reduce exposures to a level of risk that is acceptable considering the hypersusceptibility of the em-

365. The NRC's determination that there is no sex-linked difference in radiosensitivity is based on consideration of the respective gonadal physiologies of males and females. See *supra* text accompanying notes 71-80. Despite the difference in the male and female reproductive systems, a "reasoned hypothesis of special susceptibility because of sex is largely without basis." Nothstein & Ayres, *supra* note 361, at 246. See also Comment, *supra* note 360, at 759.

366. Comment, *supra* note 360, at 759.

367. 50 Fed. Reg. at 51,996.

368. Professor Williams, the premier academic critic of corporate fetal-protection plans that exclude all fertile women from fetotoxic workplaces, does not recognize the differential risk rationale the NRC is now using to support restrictive standards for pregnant radiation workers. Williams, *supra* note 347, at 641. Although Williams' arguments are not specific to radiation, and were penned prior to the NRC's proposal, they are influential and are in conflict with a regulatory attempt to differentiate pregnant women from other workers.

Williams does not concede that the risk of injuring the unborn is greater through direct exposure of the embryo/fetus than through exposure of either parent prior to conception. She correctly contends that many of the fetotoxic substances that are used to justify excluding fertile women from jobs may also act as mutagens and damage the genetic material in sperm. Since fetotoxins may also pose a threat to the unborn through paternally mediated mechanisms, Williams argues that exclusion of fertile women is not justified. "If the health of offspring can be affected through either sex, the fact that one or more of the particular mechanisms through which the offspring may be affected is sex specific is irrelevant in this context." *Id.* at 667. She characterizes fetal protection plans as instances of "parental exposure; maternal exclusion," *id.* at 653, and discounts evidence of any differential risk: "There is simply no basis for resolving doubts about the evidence by applying a policy to women but not to men on the *unsubstantiated generalization* that the fetus is placed at greatest risk by workplace exposures of the pregnant women." *Id.* at 663 (emphasis added).

At least in the case of exposure to radiation, Williams' arguments are weak. Far from being an "unsubstantiated generalization," the heightened radiosensitivity of the embryo/fetus is well-documented. See *supra* note 361. Thus, Williams mischaracterizes the nature of fetal protection plans. This is not a case of "parental exposure; maternal exclusion." Exclusion of the woman is based not on the fear of maternally mediated harm to reproductive health, but rather on the fear of direct exposure to the embryo/fetus. A more apt characterization of fetal protection plans would be "parental exposure, embryo/fetal exposure, maternal exclusion." From this perspective, maternal exclusion should be considered unacceptable when the woman is not pregnant and when there is no evidence of a significantly greater risk from direct exposure of the embryo/fetus than from parental exposure. With radiation, such a differential risk exists and it is the basis on which the NRC has proposed to restrict the exposure of pregnant women.

bryo/fetus.³⁶⁹ Were such controls possible, the ALARA principle would mandate the reduction of all exposures to the point where the risk to the embryo/fetus would be "acceptable" and, thus, would not permit differential treatment of pregnant workers. However, both the current exposure limits and the proposed Standards are at levels where the difference in radiosensitivity between an embryo/fetus and an adult justifies regulatory differentiation of pregnant workers.

There are strong economic arguments against setting standards to protect the small percentage of the workforce that is hypersusceptible:

[I]t may be economically counterproductive to require industry to ensure fetally safe environments if the expense of doing so greatly exceeds the cost of providing an environment that is safe for adults. It is analogous to requiring the employer to maintain a working environment that does not irritate a person who has a severe allergy to a work environment substance when the substance causes little or no harm to persons without the allergy. In such a case, it makes more economic sense to remove the allergic worker than to incur a substantial cost to adjust the exposure level for the comfort of the allergic person.³⁷⁰

It is also important to note that the cost of equipment to control exposures is often exponentially related to its efficiency. A device that can lower radiation exposures by ninety-nine percent may be drastically more expensive than one that can lower exposures by ninety percent. It may therefore be economically feasible to achieve acceptable levels of risk for adults in the workforce but not feasible to attain the same risk level for the embryo/fetus. It can be inferred that the NRC's decision to propose differential standards is based on a determination that it is not feasible to reduce all exposures to protect adequately the embryo/fetus.

Finally, the NRC's proposal to restrict the exposure of pregnant women is different from programs that restrict the employment opportunities of all fertile women. The NRC recognized that recommendations to limit the exposure of all fertile women were unnecessary and overinclusive.³⁷¹ However, corporate programs that prohibit employment of fertile women in jobs that involve exposures to fetotoxins are not

369. The technical infeasibility of reducing exposures below mutagenic levels—i.e., below levels that pose unacceptable risks via the preconception, parentally mediated pathways of both men and women, but not below levels toxic to the fetus—has been postulated as one explanation for the focus of exclusionary policies on women. Rothstein, *Reproductive Hazards and Sex Discrimination in the Workplace: New Legal Concerns in Industry and on Campus*, 10 J.C. & U.L. 495, 511 n.11 (1983-84).

370. Furnish, *supra* note 355, at 85. The analogy between an allergy and a pregnancy is instructive even though it is rough. Unlike an allergy, pregnancy is a condition that a woman can choose to control and has a finite duration. Both of these attributes of pregnancy argue against forcing employers to make large expenditures to render a workplace safe for the embryos/fetuses of the small number of workers who choose to become pregnant. It would be much more cost-effective for the employer simply to provide alternative employment that does not involve exposure or to provide economic support during maternity leave.

371. See *supra* text accompanying notes 279-99 and notes 341-42.

uncommon.³⁷² Proponents of these programs claim they are necessary to protect the embryo/fetus during the vulnerable period prior to the discovery of a pregnancy.³⁷³ Rather than take the draconian step of restricting the exposure of all fertile women, the NRC has proposed lowering the limits applicable to both sexes³⁷⁴ and encouraged instructions to employees regarding the risk to the embryo/fetus.³⁷⁵ Both of these steps will minimize the risk to the embryo during the vulnerable predetection period. Only after the detection and voluntary declaration of a pregnancy does NRC propose disparate treatment of female

372. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 65, at 251-67 (1985) (outlining fetal protection policies of American Cyanamid, Shell Oil, E.I. du Pont de Nemours, and Exxon Chemical Americas); Bayer, *The Cost of Fetal Protection: Women, Work and Reproductive Hazards*, 12 HASTINGS CENTER REP. 14 (1982) (reporting "voluntary" sterilization of five women so they could keep their jobs with American Cyanamid); *Wright v. Olin Corp.*, 585 F. Supp. 1447 (W.D.N.C. 1984), *vacated*, 767 F.2d 915 (4th Cir. 1984) (pyrrhic victory in defense against Title VII challenge to fetal vulnerability program that excluded fertile women from specific jobs); Williams, *supra* note 347, at 641 (listing exclusionary policies against fertile women at General Motors, St. Joe Minerals, B.F. Goodrich, American Cyanamid, Allied Chemical, Eastman Kodak, and Firestone Tire and Rubber).

373. Fetal protection programs are discussed in OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 65. See also Howard, *Hazardous Substances in the Workplace: Implications for the Employment Rights of Women*, 129 U. PA. L. REV. 798 (1981); Williams, *supra* note 347; Note, *supra* note 361; Comment, *supra* note 360.

Exclusion of all fertile women appears to be a grossly overinclusive response to the risk of fetal harm. While an employer's interest in preventing fetal harm should not be discounted, society's interest in equal employment opportunities is no less important. To the extent these interests are contradictory, the employer should narrowly tailor his or her health protection policies to optimize all relevant interests. Such optimization cannot be accomplished by denying to all women, on the premise that they are fertile and therefore possibly pregnant, employment in environments that may be fetotoxic. See *Wright v. Olin Corp.*, 697 F.2d 1172, 1182 (4th Cir. 1982) ("Any woman age 5 through 63 is assumed to be fertile . . .").

Treating all women as perpetually pregnant is unnecessary for several reasons. First, only a small percentage of fertile women employees actually become pregnant. Pregnant workers constituted approximately 9% of the ever-married women of reproductive age in the labor force in 1972. Williams, *supra* note 347, at 696 (citing U.S. PUB. HEALTH SERV., U.S. DEP'T OF HEW, *ADVANCE DATA: PREGNANT WORKERS IN THE UNITED STATES 1* (1977)).

Second, approximately 80% of the working women that became pregnant in that year chose to do so. Williams, *supra* note 347, at 697 n.319 (citing U.S. PUB. HEALTH SERV., U.S. DEP'T OF HEW, *WANTED AND UNWANTED BIRTHS REPORTED BY MOTHERS 15-44 YEARS OF AGE: UNITED STATES, 1976*, at 3, Table 1 (1980)). If informed of occupational hazards, these women have the incentive to minimize the risk to their offspring. The existence of efficient birth control methods also argues against the paternalistic treatment of women as having no control over their reproductive capability.

Finally, methods that allow early pregnancy detection minimize the period of exposure of an unknown embryo. Williams, *supra* note 347, at 697. Pregnancies can be detected by blood tests eight to ten days, and by urinalysis four to five weeks, after conception. *Id.* at 697 n.318. By minimizing the ambient levels of fetotoxins, informing female employees of the risk posed to the embryo/fetus, and encouraging the use of reliable birth control methods, employers can help reduce the risk to the embryo/fetus prior to the discovery of a pregnancy to an acceptable level. See Comment, *supra* note 360, at 755; Andrade, *The Toxic Workplace: Title VII Protection for the Potentially Pregnant Person*, 4 HARV. WOMEN'S L.J. 71 (1981).

374. 50 Fed. Reg. at 52,003.

375. 10 C.F.R. § 19.12 (1986); OFFICE OF STANDARDS DEVELOPMENT, *supra* note 217.

employees.³⁷⁶

Because the NRC's proposed Standards fit the constraints outlined above, they are an appropriate and effective response to a serious health hazard. The focus of the debate must therefore shift to the propriety of Title VII's statutory prohibition of all reproductive health programs that unavoidably entail sexually disparate impacts. The reproductive risk from occupational exposure to radiation poses a dilemma that Title VII does not adequately address.³⁷⁷ The Pregnancy Discrimination Act categorically prohibits any disparate treatment of a pregnant radiation worker. However, the NRC's proposals are the only feasible means of preventing an unacceptable risk of embryo/fetal injury. Because the NRC does not have alternative methods of protecting prenatal health, Title VII must either be amended by the legislature or construed by the courts to permit this limited differential treatment of pregnant workers.³⁷⁸

376. 50 Fed. Reg. at 52,009.

377. To postulate an unresolved conflict between the NRC's proposed standards and Title VII, one must assume that the NRC's proposal to differentiate pregnant women will survive judicial review. Two challenges to the NRC's standards can be expected. First, the NRC's restrictive pregnancy limits will be attacked on the ground that the scientific evidence does not substantiate the need for, or the stringency of, the standard. In view of the sexually disparate impact of the standard, potential litigants may hope that the courts will be less deferential to the NRC and will hold the Commission to a high standard of scientific proof. *See American Petroleum Inst. v. OSHA*, 581 F.2d 493 (5th Cir. 1978), *aff'd sub nom. Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980) (invalidating benzene standard due to OSHA's failure to quantify benefits to be achieved by reducing limit from ten to one part per million).

Second, an equal protection challenge is likely. However, claims that pregnancy discrimination violates the equal protection clause have not met with much favor from the courts. Reduced to its most fundamental principle, equal protection analysis condemns both the differential treatment of groups that have similar characteristics and the similar treatment of groups that have different characteristics. Pregnancy is not a characteristic shared by men and women. Moreover, pregnancy is not a condition shared by all women. Therefore, arguably, the equality principle does not apply when men and women, or women and men as opposed to pregnant women, are treated differently with respect to the uncommon characteristic of pregnancy. While there is a strong argument that discrimination on the basis of a characteristic that is inextricably linked to one sex is by definition sex discrimination, the Supreme Court has generally held that discrimination on the basis of pregnancy is not sex discrimination *per se*. *See, e.g. Geduldig v. Aiello*, 417 U.S. 484 (1974) (state disability insurance program that exempted from coverage work loss resulting from pregnancy does not violate the equal protection clause); *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976) (under Title VII, employer's disability plan does not discriminate on the basis of sex by denying benefits for disabilities caused by pregnancy). The desire to overrule the *Gilbert* decision was an explicit reason for passage of the Pregnancy Discrimination Act. 42 U.S.C. § 2000e(k) (1982). *See HOUSE COMM. ON EDUCATION AND LABOR, PROHIBITION OF SEX DISCRIMINATION BASED ON PREGNANCY*, H.R. No. 948, 95th Cong., 2d Sess. (1978), *reprinted in 1978 U.S. CODE CONG. AND ADMIN. NEWS* 4749, 4750.

While the authors do not intend to demean the merits of these arguments, it is assumed here that the NRC's proposed pregnancy standards will survive judicial review.

378. Several commentators have also reached this conclusion. *See* Furnish, *supra* note 355, at 116 (arguing for legislative amendment of Title VII to "provide a conditional defense to employers and a right to pregnant women to avoid fetal harm"); Howard, *supra* note 373, at

CONCLUSION

The NRC's proposed revision of its Standards for Protection Against Radiation should be commended by all concerned with occupational health. From a general health perspective, support for the proposal should be enthusiastic. The NRC has successfully addressed many of the major deficiencies of its current Standards. For instance, both annual and cumulative exposures of the most critical tissues would be significantly reduced. Cumulative exposures would be limited in a manner that removes agency paternalism and an employer's incentive to discriminate on the basis of age. The proposal would also make the ALARA provision mandatory and promises a reduced role for cost-benefit analysis. Most importantly, the NRC has recognized that the threshold theory is inapplicable to radiation injury and has predicated its proposed Standards on a clear, health-based rationale. By first quantifying risk and then judging the acceptability of that risk, the NRC has developed a sound method of establishing occupational exposure standards. This approach also sets an important precedent for all federal agencies to follow in regulating exposures to other nonthreshold toxicants in the workplace.

From a reproductive health perspective, the NRC's proposed Standards should also receive support. Any decrease in occupational exposure will lower the probability of injury to future generations. Further, the problem of direct exposure of the radiosensitive embryo/fetus is addressed. Unfortunately, the enthusiasm that should accompany any regulatory action to protect prenatal health must be dampened by the proposal's impact on the employment opportunities of pregnant women. The NRC cannot, however, avoid this impact and adequately address embryo/fetal health. Because the NRC has framed its proposal to protect prenatal health while minimizing the impact on equal employment opportunities, the proposed Standards should be positively received.

801 (judicial modification of Title VII "is the best solution to the problem of discriminatory practices resulting from occupational exposure to hazardous substances"); Comment, *supra* note 360, at 757 ("preferred approach to the problem of reconciling equal employment opportunity with fetal protection is legislative amendment").