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NOTES

MEDICAL AND DENTAL X-RAYS — A TIME FOR RE-EVALUATION AND STATE ACTION

I. Introduction

In 1956, the National Academy of Sciences in a report on "The Biological Effects of Atomic Radiation" warned the public of the serious consequences that may flow from any type of radiation exposure.¹ The report set forth the relationship between low-level exposure, that type of exposure which is present in the medical and dental use of X-rays, and long-range biological effects.² Because of the possibility of such long-range effects, the Academy recommended that the medical authorities take prompt action to eliminate all unnecessary radiation in the use of X-rays.³

Despite the strong language used by the Academy, and the lapse of eleven years, the problem of excessive radiation exposure to patients and personnel by medical and dental X-rays is still very much with us.⁴ This Note is an attempt to set forth clearly and precisely the hazards of any unnecessary radiation; the existence of such unnecessary radiation to an alarming extent in the medical and dental use of X-rays; the inadequacies inherent in our judicial system for compensating the victim of such unnecessary exposure; and the need for state legislative and administrative action to eliminate all unnecessary radiation exposure in the medical and dental field.

The significance of medical and dental use of X-rays is indicated by the fact that such use constitutes an estimated ninety-six percent of all man-made radiation to which the population is exposed.⁵ Thus,

it is apparent that diagnostic medical [and dental] x-ray exposure is by far the most important contributor to the dose received by the population from man-made sources of ionizing radiation and any . . . group genuinely interested in reducing population exposure to ionizing radiation will devote most of its attention to this problem.⁶

However, it has been the practice of national, state and city radiation control groups to concentrate their efforts on the hazards of radioactive fallout, nuclear reactors and radioisotopes.⁷ This Note seeks to correct that situation by pro-

1 NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *THE BIOLOGICAL EFFECTS OF ATOMIC RADIATION* (summary reports 1956) [hereinafter cited as NAS REP.].

2 *Id.* at 15-16.

3 *Id.* at 28.

4 See Section III of this Note, "Unnecessary Radiation in Medical and Dental X-Ray Diagnosis."

5 Baumgartner & Blatz, *Control of Common Radiation Hazards in New York City*, 76 PUB. HEALTH REP. 583, 585 (1961). See H. BLATZ, INTRODUCTION TO RADIOLOGICAL HEALTH vi (1964); K. Z. Morgan, Radiation Protection, Past, Present and Projection, Aug. 24-26, 1966, at 18-20 (presented at the Conference on Principles of Radiation Protection, Oak Ridge, Tennessee); Haddon & Morgan, *Frequency of Medical X-ray Examinations in Monroe County, New York*, 80 PUB. HEALTH REP. 515 (1965); Menczer, *The Open-Ended Metal Column for Dental X-Ray Machine*, 73 J.A.D.A. 1083, 1088 (1966).

6 K. Z. Morgan, Radiation Hazards in Metropolitan Areas, June 1964, at 8 (submitted as a paper to the World Health Organization, Geneva, Switzerland).

7 *Id.* at 5.

posing legislation and administrative regulations for the purpose of controlling the use of X-rays in the medical and dental field.

This Note is restricted solely to the dangers of the long-range biological effects of low-level radiation exposure and does not cover the acute and readily discernible⁸ radiation injuries of higher levels of dosage. Readily discernible radiation injuries, such as radiation burns, do not constitute a widespread problem in the medical and dental field, and when they do occur the judicial remedies are adequate to compensate the victim.⁹

II. Latent Radiation Injuries: An Unseen Danger

The need for corrective measures in the area of medical and dental use of X-rays can be appreciated fully only when one has a basic understanding of the biological effects of radiation. The principal purpose of this section is to provide that basic understanding.¹⁰

The radiation exposure to individuals from medical or dental X-rays is that of low-level doses received sporadically over a long period of time. This type of radiation exposure can result in injurious effects, but generally only many years after the initial exposure.¹¹ Because the biological effects of low-level radiation exposure are latent, injury from medical or dental X-ray exposure is difficult to detect. The detection of injuries from medical or dental X-ray exposure is further complicated by the fact that these effects are similar to existing diseases which are not radiation-caused.¹² Despite the difficulty in observing the injurious effects of medical or dental X-rays in the average individual, such effects *do* exist as will be shown in the following discussion.¹³

8 By "readily discernible" is meant that the injury is apparent within a few hours, days or weeks.

9 See Annot., 41 A.L.R.2d 329 (1955); Annot., 83 A.L.R.2d 7, 166 (1962).

10 For a more detailed discussion of radiation and its long-term biological effects see D. BARNES & D. TAYLOR, *RADIATION HAZARDS AND PROTECTION* 19-28 (2d ed. 1963); H. BLATZ, *supra* note 5, at 102-11; J. SCHUBERT & R. LAPP, *RADIATION: WHAT IT IS AND HOW IT AFFECTS YOU* 65-87, 181-201 (1963); Report of the United Nations Scientific Committee on the Effects of Atomic Radiation, 17 UN GAOR, Supp. 16, at 9-10, UN Doc. A/5216 (1962); NAS REP.; Estep & Forgotson, *Legal Liability for Genetic Injuries from Radiation*, 24 LA. L. REV. 1 (1963); K. Z. Morgan, *Medical X-Ray Exposure*, 24 AM. INDUS. HYGIENE ASS'N J. 588 (1963); Scott, *The Clinical Radiologist and the Problems of Radiation Hazards*, 170 J.A.M.A. 421 (1959).

11 Powell, *Effects of Radiation on Man*, 12 VAND. L. REV. 81, 85-92 (1958).

12 See Report of the United Nations Scientific Committee on the Effects of Atomic Radiation, 17 UN GAOR, Supp. 16, at 9-10, UN Doc. A/5216 (1962) [hereinafter cited as UN REP.].

13

It is universally agreed today that radiation causes certain biological changes and that in the case of human beings, the changes are invariably undesirable or harmful. . . . [I]t is believed that small amounts of radiation exposure can cause barely detectable or sometimes undetectable genetic changes and also slight increases in the statistical incidence of certain radiation-induced diseases such as leukemia and bone tumors. . . . There is no immediately detectable effect of small exposures upon an individual, nor would one expect any apparent effect to be evident in immediate descendants, although damaged genes might be passed along from generation to generation to appear later. Because of the absence of evidence of harm it is so difficult to control the small but unnecessary exposures. If the exposure of human beings to radiation were to continue to increase and produce increased genetic damage, there would undoubtedly be a gradual deterioration of the race.

Blatz, *Reduction of Dose in Medical and Industrial Radiography*, 52 AM. J. PUB. HEALTH 1385 (1962). See also UN REP. 9-11.

The biological effects of exposure to ionizing rays are both somatic¹⁴ and genetic.¹⁵ These effects, either somatic or genetic, depend on a number of factors; the principal ones are the quantity of radiation received and the area of the body exposed. The greater the dose of radiation, the larger the area of the body exposed and the more sensitive the parts of the body involved, the greater will be the damage. It is also important to note that different types of cells react differently to radiation: young, rapidly developing cells are very sensitive, while fully developed cells are relatively resistant.

A. Somatic Effects

The biological effects of a somatic nature that can result from medical or dental X-ray exposure are: (1) the induction of malignancies such as leukemia, epithelioma, bone tumors, depilation and dermatitis;¹⁶ (2) local effects on tissues;¹⁷ (3) effects on growth and development;¹⁸ (4) shortening of life span.¹⁹

Of particular importance is radiation-induced leukemia, because in all the countries for which mortality data are available, "the recorded death rates from the various forms of leukemia . . . have been rising since the turn of the century."²⁰ The incidence of leukemia "in the U.S. — especially for white people — is among the highest in the world and the upward trend still continues . . ."²¹ The degree to which this leukemia incidence is related to medical exposure is not known, but in all likelihood, some of it can be traced to such exposure.²² It has been well established that radiation in high doses will induce various forms of cancer, especially leukemia.²³ Furthermore, during the past decade scientific knowledge of the somatic effects of radiation has increased substantially and it is now evident that certain transient somatic effects can be induced by relatively low doses of radiation.²⁴ Therefore, as K. Z. Morgan has cautioned,

it is prudent to assume that all exposure to ionizing radiation increases the probability of certain types of damage such as leukemia or bone tumors and as a consequence, radiation exposure should be received only when the resulting benefits are considered to outweigh the probability of damage.²⁵

B. Genetic Effects

Every cell in the human body contains genes, hereditary factors that have

14 Somatic effects are biological effects occurring during the lifetime of the exposed individual.

15 Genetic effects are the effects on generations yet unborn.

16 UN REP. 10; Corday & Jaffe, *Routine Cardiac Fluoroscopy—An Unnecessary Health Hazard*, 172 J.A.M.A. 1127 (1960); K. Z. Morgan, *supra* note 10, at 597; R. H. Morgan, *Radiation Control in Public Health*, 76 PUB. HEALTH REP. 571, 573 (1961).

17 UN REP. 10.

18 *Id.*

19 *Id.* K. Z. Morgan, *supra* note 10, at 597; R. H. Morgan, *supra* note 16, at 573.

20 UN REP. 10.

21 K. Z. Morgan, *supra* note 10, at 597.

22 *Id.* at 597-99.

23 *See* UN REP. 10-19; K. Z. Morgan, *supra* note 10, at 599; R. H. Morgan, *supra* note 16, at 573.

24 *See* UN REP. 34.

25 K. Z. Morgan, *supra* note 10, at 599.

been passed on from generation to generation. The genes are combined to form genetic material called chromosomes. A human body cell is comprised of forty-eight chromosomes, twenty-four of which were inherited from the egg cell and twenty-four from the sperm cell. The genes which are present in the fertilized egg generally remain unchanged as the cells divide and the human body is formed. The genes can be changed by certain physical agents, such as radiation, heat, and some chemicals.²⁶ The most important of these agents is radiation "because it is capable of penetrating *in unaltered form* into the reproductive tissues themselves and acting directly on the germ cells (sperm, egg, precursors) and their nuclear material."²⁷ When a gene is changed it becomes permanently altered, a process known as mutation. This mutation of the gene, which produces some change in the characteristics of the organism carrying it, is then duplicated in each subsequent cell division.²⁸ That is, the hereditary defect involved in the mutation "will be present in every cell of the offspring to whom it is transmitted via egg or sperm and no tissue can escape the consequences of the defect."²⁹

From the standpoint of public health, the most important aspect of radiation-induced mutations is that the altered genes result in deviations from the norm in the offspring of the irradiated parents, and ultimately lead to some kind of harmful effect.³⁰ "In extreme cases the harmful effect is death itself, or loss of the ability to produce offspring, or some other serious abnormality."³¹ Of even greater ultimate importance, however, are the cases that involve much smaller deviations from the norm, such as decreased longevity, increased susceptibility to disease, and decreased fertility.³² This is because the smaller deviations affect many more people.³³

The effect of a radiation-induced mutation, an altered gene, is rarely detectable in the first generation offspring because the mutant gene is usually recessive or masked.³⁴ Thus, "[i]f a child gets from one parent a mutant gene, but from the other parent a normal gene belonging to that pair, then the normal gene is very likely to be at least partially dominant,"³⁵ and the child will not bear the full brunt of the genetic damage. Therefore,

contrary to public opinion, freaks and monstrosities do not often occur in the first generation after a [parent] is irradiated. Usually the deviations caused by the damaged gene in the first offspring are so minute and subtle that recognition is extremely difficult. The full expression of the damage

26 See NAS REP. 9; Estep & Forgotson, *supra* note 10, at 21; Martin, *Necessity and Means of Protecting Patients in Diagnostic and Therapeutic Radiology*, 1 PROCEEDINGS OF THE COLLEGE OF RADIOLOGISTS OF AUSTRALASIA 103, 104 (1957).

27 Estep & Forgotson, *supra* note 10, at 21.

28 See NAS REP. 9; Martin, *supra* note 26, at 104.

29 Scott, *supra* note 10, at 423.

30 *Id.*; NAS REP. 12.

31 NAS REP. 12. See also Estep & Forgotson, *supra* note 10, at 22.

32 See NAS REP. 12.

33 The reason smaller deviations affect many more people than the serious abnormalities is because for them to occur only one parent need have a mutant gene, while for the serious abnormalities to occur both parents must possess the mutant gene. This is explained more fully in the following discussion.

34 See NAS REP. 12; Estep & Forgotson, *supra* note 10, at 22; Scott, *supra* note 10, at 423.

35 NAS REP. 12.

comes in subsequent generations when there is mating of those with similarly damaged genes.³⁶

However, even when the recessive mutant gene is paired with a normal and dominant gene it still has some detrimental effect.³⁷ The risk of this type of damage applies to many individuals, indeed to every descendant who receives the mutant gene.

There is general agreement among geneticists and the official radiation protection groups that there is no threshold dose of radiation which must be exceeded before any harmful mutations occur.³⁸ That is, even the smallest amount of radiation can induce some mutations, and therefore to some extent be genetically harmful.³⁹ It is important to note that the genetic effects of these small doses of radiation are not so minute and negligible as to be disregarded. Moreover, since the genetic damage caused by radiation is largely *irreversible*⁴⁰ and thus *cumulative*⁴¹ in effect, the small doses of radiation can result in quite significant genetic damage over a period of years. Therefore, the total accumulated dose of radiation received during a person's life is the vital factor from the standpoint of radiation-induced genetic damage. The National Academy of Sciences in its report on "The Biological Effects of Atomic Radiation" destroyed the myth of a possible safe rate of radiation exposure by their statement:

It has sometimes been thought that there may be a *rate* (say, so much per week) at which a person can receive radiation with reasonable safety as regards certain types of direct damage to his own person. But the concept of a *safe rate* of radiation simply does not make sense if one is concerned with genetic damage to future generations. What counts, from the point of view of genetic damage, is not the rate; it is the *total accumulated dose to the reproductive cells of the individual from the beginning of his life up to the time the child is conceived*.⁴²

In light of the serious consequences of radiation exposure, it is imperative that our society require all radiation exposure to be kept as low as possible.⁴³ Since medical and dental X-rays are the chief source of radiation exposure in the United States,⁴⁴ it has been recommended that

the medical [and dental] authorities of this country initiate a vigorous movement to reduce the radiation exposure from X-rays to the lowest limit consistent with medical necessity; and in particular that they take steps to assure that proper safeguards always be taken to minimize the radiation dose to the reproductive cells.⁴⁵

36 Scott, *supra* note 10, at 423.

37 NAS REP. 12.

38 See NAS REP. 15; Blatz, *supra* note 13; Estep & Forgotson, *supra* note 10, at 23; Martin, *supra* note 26, at 104; Scott, *supra* note 10, at 423.

39 *Id.*

40 Martin, *supra* note 26, at 104; Scott, *supra* note 10, at 423.

41 *Id.*

42 NAS REP. 16.

43 *Id.* at 28.

44 See, e.g., H. BLATZ, *supra* note 5, at vi; K. Z. MORGAN, *supra* note 5, at 18-20; Haddon & Morgan, *supra* note 5; Menczer, *supra* note 5, at 1088.

45 NAS REP. 28.

Although the National Academy of Sciences made this strong recommendation for corrective action in 1956, unnecessary radiation exposure to patients and personnel still exists in many medical and dental facilities.⁴⁶

III. Unnecessary Radiation in Medical and Dental X-Ray Diagnosis

Due to the probability of long-range deleterious effects from low doses of radiation, it is imperative that all unnecessary radiation be eliminated. Unnecessary radiation in the area of medical and dental X-ray diagnosis is defined as that radiation which can be eliminated without impairing the quality and quantity of diagnostic information obtainable from the X-ray examination. It is important to thoroughly understand this definition of unnecessary radiation, and also to keep in mind that this Note is concerned solely with that radiation which can be eliminated without adversely affecting clinical results. The benefits of radiation in the healing arts are beyond question and it is not even remotely suggested that these benefits be curtailed. The principal purpose of this section is to show that unnecessary radiation does exist in the medical and dental use of X-rays.⁴⁷

A. Medical X-Ray Diagnosis

In evaluating the unnecessary radiation present in a medical X-ray installation, two factors must be considered: (1) the equipment and its accessories, and (2) the manner in which the equipment is used.⁴⁸ Each of these two factors must be examined in relation to the two types of medical X-ray examinations, radiography and fluoroscopy.

1. X-Ray Equipment

The standards for protection against unnecessary radiation attributable to medical X-ray equipment have been quite clearly expressed by the National Council on Radiation Protection (NCRP) in a series of handbooks, the latest being Handbook 76.⁴⁹ It will be assumed throughout this discussion that failure to comply with these standards leads to unnecessary radiation exposure.⁵⁰

⁴⁶ See Section III of this Note, "Unnecessary Radiation in Medical and Dental X-Ray Diagnosis."

⁴⁷ "It is generally agreed that the medical and dental use of X-rays constitutes, by far, the greatest radiation exposure of the population, the one that can most readily be reduced without serious interference with the practice of radiology." H. BLATZ, *supra* note 5, at vi.

⁴⁸ *Id.* at 246.

⁴⁹ NATIONAL COMMITTEE ON RADIATION PROTECTION AND MEASUREMENTS, MEDICAL X-RAY PROTECTION UP TO THREE MILLION VOLTS 11-18 (National Bureau of Standards Handbook 76, 1961) [hereinafter cited as HANDBOOK 76].

⁵⁰ Handbook 76 is used as the standard for evaluating unnecessary radiation exposure because it is universally regarded as the most authoritative statement on the subject of X-ray protection. The Subcommittee which prepared this Handbook consisted of the recognized authorities in the field of X-ray protection. See HANDBOOK 76, *supra* note 49, at v-vi.

a. Radiography⁵¹

In radiography the deficiencies in X-ray equipment which contribute to unnecessary radiation exposure are: inadequate cone or diaphragm, inadequate filtration, inadequate beam alignment, inadequate protective housing around the tube head, and a mechanical rather than an electronic timer.⁵²

An inadequate cone or diaphragm, or even worse none at all, results in a lack of proper collimation of the X-ray beam. That is, the X-ray beam covers an area greater than that under diagnostic study. The lack of proper collimation results in a substantially higher gonadal dose⁵³ than when the beam is collimated to only the diagnostic area by the use of a cone or diaphragm.⁵⁴ Any part of the X-ray beam that covers an area not under diagnostic study is unnecessary radiation and should be eliminated by cones or diaphragms.⁵⁵ Dr. W. G. Scott estimates that the use of cones or diaphragms would reduce the radiation dose to the patient by 15 to 30%, without impairing the diagnostic quality of the X-ray examination.⁵⁶ The magnitude of the hazard involved and the ease with which corrections may be made tempt one to speculate that all X-ray machines used in the medical profession are equipped with the proper collimating devices. This, however, is definitely not the situation in the United States today. The need for corrective devices to collimate the X-ray beam is graphically illustrated by the results of the X-ray protection surveys presented in Appendix A. For example, 57% of the machines surveyed in Polk County, Florida, were deficient in collimating the X-ray beam, as were 41% in Los Angeles, 66% in New York City, 58.3% in Baltimore, and 33.6% in Texas.⁵⁷

The second major equipment deficiency leading to unnecessary radiation in radiography is inadequate filtration of the X-ray beam.⁵⁸ The X-ray beam contains X-rays of varying energies. The X-rays at the lower end of the energy spectrum are called "soft" X-rays, while those at the upper end of the spectrum are called "hard" X-rays. The hard X-rays pass through the patient and strike

51 Radiography is the procedure whereby a picture is produced upon a sensitive surface, such as a photographic plate, by means of X-rays, with the film being later developed for diagnostic study.

52 H. BLATZ, *supra* note 5, at 246-47. See K. Z. Morgan, *supra* note 5, at 10-12; K. Z. Morgan, Maximum Permissible Exposure to Ionizing Radiation, April 13-15, 1966, at 12 (presented at the Conference on the Use of X-Rays in Medicine and Industry, Miami, Florida); Blatz, *supra* note 13, at 1387; Brodeur & Seagle, *Selecting Surveyors of X-ray Equipment*, 79 PUB. HEALTH REP. 317, 319-20 (1964); Hodges, *Health Hazards in the Diagnostic Use of X-Rays*, 166 J.A.M.A. 577, 582 (1958); Stahl, *X-Ray Protection Techniques*, 75 PUB. HEALTH REP. 513, 518-22 (1960).

53 Gonadal dose is that dose which produces genetic effects.

54 The use of an adjustable round lead diaphragm in a chest examination can reduce the male gonadal exposure/film by 89 percent over that with no collimation. Feldman, Babcock, Lanier & Morkovin, *Gonadal Exposure Dose from Diagnostic X-Ray Procedures*, 71 RADIOLOGY 197, 206 (1958).

55 For articles calling for a reduction in beam size by cones or diaphragms and thus the elimination of unnecessary radiation, see K. Z. Morgan, Maximum Permissible Exposure to Ionizing Radiation, April 13-15, 1966, at 12 (presented at the Conference on the Use of X-Rays in Medicine and Industry, Miami, Florida); Baumgartner & Blatz, *supra* note 5; Blatz, *supra* note 13, at 1387; Brodeur & Seagle, *supra* note 52; Hodges, *supra* note 52, at 582; Stahl, *supra* note 52, at 518.

56 Scott, *supra* note 10, at 426.

57 See Appendix A *infra*.

58 For articles concerned with the elimination of unnecessary radiation by the use of adequate filtration, see Brodeur & Seagle, *supra* note 52, at 319-20; Hodges, *supra* note 52, at 582; Stahl, *supra* note 52, at 520.

the photographic plate, thus creating the X-ray picture. The soft X-rays generally do not reach the photographic plate, but rather are absorbed by the skin and outer regions of the patient's body. Because the soft X-rays do not reach the photographic plate, they provide no useful diagnostic information, and should be eliminated as harmful and unnecessary radiation.⁵⁹ The soft X-rays can be easily removed by placing filters⁶⁰ in the primary beam. The NCRP recommends that the total filtration permanently in the useful beam should not be less than 2.5 millimeters of aluminum equivalent.⁶¹ Scott estimates that the radiation dose to the patient could be reduced by more than 50% by the use of 2 millimeters of aluminum equivalent filtration.⁶² The extent to which the X-ray machines in the medical profession have been equipped with adequate filtration is illustrated by the results of the X-ray protection surveys presented in Appendix A. For example, 40% of the machines surveyed in Polk County, Florida, were deficient in filtration, as were 45% in Los Angeles, 25% in New York City, 52% in Baltimore, and 36% in Texas.⁶³

The third common X-ray equipment deficiency which leads to unnecessary radiation to the patient in radiography is inadequate beam alignment.⁶⁴ When the alignment of the X-ray beam is off-center the X-ray technician increases the beam size in order to cover the entire area of the photographic plate.⁶⁵ The increase in beam size due to misalignment results in unnecessary exposure to the patient because areas of his body not under diagnostic study are covered by the X-ray beam. This deficiency can be easily overcome in most X-ray machines by the installation of a beam-defining light in the tube head housing. Yet the Public Health Service survey of 1964 indicated that 37% of the X-ray machines in the United States were deficient in beam alignment.⁶⁶

Other X-ray equipment deficiencies which lead to unnecessary radiation in radiography are inadequate protective housing around the tube head, and a mechanical rather than an electronic timer.⁶⁷ An inadequate protective housing around the tube head results in excessive leakage radiation and thus unnecessarily irradiates the patient and operating personnel. Likewise, an electronic timer reduces radiation exposure because high-speed film can be used with it to cut the exposure time to a fraction of a second.⁶⁸

*b. Fluoroscopy*⁶⁹

The deficiencies in fluoroscopic equipment which contribute to unnecessary

⁵⁹ *Id.*

⁶⁰ A filter is any material which absorbs X-rays. The measure of a material's absorption quality is expressed in units of aluminum equivalent.

⁶¹ HANDBOOK 76, *supra* note 49, at 14.

⁶² Scott, *The Clinical Radiologist and the Problems of Radiation Hazards*, 170 J.A.M.A. 421, 426 (1959).

⁶³ See Appendix A *infra*.

⁶⁴ See Brodeur & Seagle, *supra* note 52, at 319-20.

⁶⁵ This is done to avoid what is commonly known as "corner-cutting."

⁶⁶ See Appendix A *infra*.

⁶⁷ H. BLATZ, INTRODUCTION TO RADIOLOGICAL HEALTH 246-47 (1964).

⁶⁸ TIME, Dec. 9, 1966, at 73.

⁶⁹ A fluoroscope consists of a fluorescent screen and an X-ray machine. The fluorescent screen is mounted in front of the X-ray tube so that the internal organs of the patient may be examined through the shadow cast by the X-rays.

radiation exposure are: inadequate filtration, inadequate target-to-tabletop distance, lack of a sensitive screen, excessive output, inadequate shutter arrangement, inadequate protective housing around the tube head, and lack of a cumulative timer.⁷⁰

Inadequate filtration in the X-ray beam in fluoroscopic examinations results in unnecessary radiation to the patient and the physician.⁷¹ Scott estimates that the radiation dose to the patient can be reduced by more than 50% by the use of three millimeters of aluminum equivalent filtration.⁷² Surveys of fluoroscopes indicate that unnecessary radiation due to inadequate filtration definitely exists, especially in regard to nonradiologists. For example, 50% of the fluoroscopes surveyed in Oregon hospitals without radiologists were deficient in filtration, while in hospitals with radiologists only 12% were deficient.⁷³ In Polk County, Florida, 36% of the fluoroscopes surveyed were deficient in filtration, as were 19% in New York City, and 63% in Baltimore.⁷⁴

An inadequate tube target-to-tabletop distance also leads to unnecessary radiation to the patient and the physician in fluoroscopic examinations.⁷⁵ The NCRP recommends a minimum distance of 18 inches.⁷⁶ Scott estimates that the utilization of the minimum distance of 18 inches will result in a radiation dose reduction of more than 10% in ordinary fluoroscopic examinations.⁷⁷ As has been repeatedly emphasized, this dose reduction in no way affects the diagnostic quality of the examination, but rather results only in the elimination of unnecessary and harmful radiation to both the patient and operator.

Another deficiency in fluoroscopic equipment which leads to unnecessary radiation is the failure to use a highly sensitive screen.⁷⁸ Screens become quite insensitive to X-rays with the passage of time, and also become outdated by modern developments. It has been estimated that a high-speed intensifying screen can reduce the radiation dose to the patient by 40 to 50%.⁷⁹

The unnecessary radiation exposure to the patient can be further reduced by periodically checking to insure that the output of the fluoroscope is at the lowest level possible. In many cases the roentgen output of a fluoroscope is not even known by the doctor in charge, and the fluoroscope is needlessly operated at a higher than necessary level.⁸⁰ Surveys of fluoroscopes validate this assertion; especially in regard to nonradiologists. For example, 34% of the fluoroscopes

70 H. BLATZ, *supra* note 67, at 246-47, 251-54; Brodeur & Seagle, *supra* note 52, at 319-20; Hale, Kusner, Gorson & Bartsch, *Radiation Safety Evaluation of Fluoroscopes*, 71 *RADIOLOGY* 227, 234 (1958); Stahl, *supra* note 52, at 523.

71 See text accompanying note 59 *supra*. For articles concerned with the elimination of unnecessary radiation by the use of adequate filtration in fluoroscopes, see Brodeur & Seagle, *supra* note 52, at 319-20; Hale, Kusner, Gorson & Bartsch, *supra* note 70, at 234; Hodges, *supra* note 52, at 582.

72 Scott, *supra* note 62, at 426.

73 See Appendix A *infra*.

74 *Id.*

75 See Brodeur & Seagle, *supra* note 52, at 319-20; Stahl, *supra* note 52, at 523-24.

76 See HANDBOOK 76, *supra* note 49, at 11.

77 Scott, *supra* note 62, at 426.

78 Blatz, *Reduction of Dose in Medical and Industrial Radiography*, 52 *AM. J. PUB. HEALTH* 1385, 1388 (1962); Brodeur & Seagle, *supra* note 52, at 319-20; Hodges, *supra* note 52, at 582.

79 Scott, *supra* note 62, at 426.

80 J. SCHUBERT & R. LAPP, *RADIATION: WHAT IT IS AND HOW IT AFFECTS YOU* 50-51 (1963).

surveyed in Oregon hospitals without radiologists had an excessive roentgen output, while only 3% of the fluoroscopes surveyed in hospitals with radiologists had an excessive roentgen output.⁸¹ In Baltimore, 40% of the fluoroscopes surveyed had an excessive roentgen output, as did 21% in Erie County, New York.⁸²

A still further deficiency in fluoroscopic equipment which results in unnecessary radiation to the patient and operator is an inadequate shutter arrangement.⁸³ A shutter arrangement should restrict the size of the useful beam to less than the areas of the barrier. For conventional fluoroscopes, this requirement is met when an unilluminated margin is left on the fluorescent screen, regardless of the position of the screen during use.⁸⁴ But, when there is an inadequate shutter arrangement, the operator is directly in the X-ray beam because there is no shielding material between part of the X-ray beam and the operator. Immediate action should be taken to eliminate this source of unnecessary radiation to the operator. The prevalence of this deficiency in fluoroscopes is illustrated by the results of surveys presented in Appendix A. For example, 78% of the fluoroscopes surveyed in Baltimore had inadequate shutter arrangement, as did 60% in New York City, 52% in California, and 20% in Texas.⁸⁵

Other deficiencies in fluoroscopic equipment which lead to unnecessary radiation are the absence of a cumulative timer⁸⁶ and inadequate protective housing around the tube head. A cumulative timer either indicates the elapsed time by an audible signal or turns off the fluoroscope when the total exposure exceeds a predetermined limit. In light of the natural tendency of a radiologist to become engrossed in his diagnosis, a cumulative timer is essential to ensure that the safe level of exposure is not exceeded. As previously pointed out, adequate protective housing around the tube head is necessary to prevent leakage radiation.

2. Operating Procedures

a. Radiography

In radiography the operating procedures which contribute to unnecessary radiation exposures are: operation of X-ray equipment without a personnel monitoring program and without an analysis of personnel shielding and positioning, lack of local shielding for the patient, slow film and improper film development, and X-ray examination of pregnant women.⁸⁷

81 See Appendix A *infra*.

82 *Id.*

83 See Brodeur & Seagle, *supra* note 52, at 319-20; Hale, Kusner, Gorson & Bartsch, *supra* note 70, at 234; Hodges, *supra* note 52, at 582; Stahl, *supra* note 52, at 523.

84 HANDBOOK 76, *supra* note 49, at 12.

85 See Appendix A *infra*.

86 Hale, Kusner, Gorson & Bartsch, *supra* note 70, at 234.

87 See K. Z. Morgan, Radiation Protection, Past, Present and Projection, Aug. 24-26, 1966, at 10-12 (presented at the Conference on Principles of Radiation Protection, Oak Ridge, Tennessee); Appleby, Hacking, Chir & Warrick, *Dose Reduction in Pelvimetry*, 31 BRITISH J. RADIOLOGY 267 (1958); Feldman, Babcock, Lanier & Morkovin, *supra* note 54; Fotopoulos, Book Review, 80 RADIOLOGY 171, 172 (1963); Hodges, Strandjord & McCrea, *A Testicular Shield*, 167 J.A.M.A. 1239 (1958); Stahl, *supra* note 52, at 515-21.

The implementation of personnel monitoring, shielding, and positioning techniques in a medical facility can greatly reduce the unnecessary radiation exposure to medical personnel. In fact, personnel monitoring should be used assiduously as the principal means of evaluating the X-ray protection program of the medical facility. But unfortunately, the practice of personnel monitoring is not universally used in medical facilities.⁸⁸ The value of the proper interplay of personnel shielding and positioning is vividly illustrated by the results achieved by a Utah survey team. It was found that, merely by changing the positions of the X-ray operators to safer locations in the room, the survey team effectuated a reduction in the radiation exposure to such operators and their assistants by 98% and 97%, respectively.⁸⁹ Regrettably, as shown by the surveys in Appendix A, personnel shielding and positioning is not used by all medical facilities.⁹⁰

The use of local shielding for the patient is another way of reducing the unnecessary radiation exposure to the patient in radiographic procedures.⁹¹ Local shielding can be utilized in several ways; the most effective is shielding the gonads directly.⁹² Adequately shielding the male gonads⁹³ during medical X-ray examinations can reduce the gonadal exposure⁹⁴ to a minimum.⁹⁵ For example, Feldman, and others, report that the proper use of a gonadal shield reduces the male gonadal dose by 94% in a pelvis examination and 91% in an abdomen and lumbar spine examination.⁹⁶ Because of the genetic effects involved, this reduction in gonadal dose is absolutely necessary when the patient is in the child-bearing age. Yet the Public Health Service report of 1964 estimated that 90%

88 See Appendix A, Medical Radiography Section, Personnel Monitoring under columns B, G, H, and J *infra*.

89 The average maximum exposure rate for operators standing in the positions they normally used prior to the survey was 260 milliroentgens per hour, whereas the average maximum rate when standing in the new positions recommended as a result of the survey was 5.7 milliroentgens per hour, a reduction of 98 percent. For assistants, the corresponding values were 145 milliroentgens per hour and 5.2 milliroentgens per hour, a reduction of 97 percent. The readings taken at the positions normally used prior to the survey were made after recommended modifications to the machines had been completed; therefore, these readings are probably lower than the actual exposures of operators prior to the survey.

Wheeler & Winn, *Utah Dental X-Ray Machine Survey, 1961-1963*, 5 RADIOLOGICAL HEALTH DATA 505, 509 (1964).

90 See Appendix A, Medical Radiography Section, Personnel Shielding under columns B, C, G, H, and J *infra*.

91 For articles recommending the use of local shielding to prevent unnecessary radiation exposure to a patient, see K. Z. Morgan, *supra* note 87, at 10; Appleby, Hacking, Chir & Warrick, *supra* note 87; Feldman, Babcock, Lanier & Morkovin, *supra* note 54; Fotopoulos, *supra* note 87, at 172; Hodges, Strandjord & McCrea, *supra* note 87; Stahl, *supra* note 52, at 519-20.

92 This can be accomplished by the use of lead aprons, a lead cup, or a shield placed between the X-ray tube and the patient. The choice of protection device will be dictated by the type of X-ray examination involved. See Hodges, Strandjord & McCrea, *supra* note 87.

93 It should be noted that gonadal shielding is much more effective in regard to males than females. This is because the male gonads are outside the body. The dose to the female gonads is primarily due to internal radiation scatter which cannot be eliminated by a small external gonadal shield. This does not mean, however, that gonadal shielding should be completely disregarded when the patient is female.

94 Gonadal exposure is that exposure having genetic effects. Thus, it is of the utmost importance that this exposure be reduced to an absolute minimum, especially when the patient is under thirty years of age.

95 Fotopoulos, *supra* note 87, at 172.

96 Feldman, Babcock, Lanier & Morkovin, *supra* note 54, at 206.

of the medical facilities in the U.S. had inadequate patient shielding.⁹⁷

Another means of reducing the unnecessary radiation exposure to the patient in radiographic procedures is the use of fast films and the proper methods of film development.⁹⁸ The new faster films reduce the dose to the patient because of the shorter exposure time needed for a suitable picture. Scott estimates that the use of new film with fast emulsion can reduce the dose by 40 to 50%.⁹⁹ Scott also estimates that by processing the films with the proper time and temperature control, and the use of recommended chemicals, the dose can be reduced by 5 to 20%.¹⁰⁰

X-ray examinations of pregnant women often result in adverse effects to the fetus, and the procedures utilized in making such examinations should be carefully analyzed. In the most authoritative article in this area, the Russells have concluded, on the basis of animal experiments, that the developing embryo is highly susceptible to the induction of malformations by means of radiation.¹⁰¹ The critical period for the majority of the gross abnormalities is the second to sixth week of gestation.¹⁰² Irradiation at a later stage of pregnancy produces less obvious and possibly more delayed effects, but in the long run may still prove to be as harmful as the gross monstrosities.¹⁰³ The results of a study undertaken by the Harvard School of Public Health indicated "that there was an increase in cancer . . . in the children whose mothers were irradiated during pregnancy and that the increase took place regardless of parity (successful deliveries), color, or sex."¹⁰⁴ Dr. Alice Stewart has also discovered a correlation between the incidence of malignant diseases in children and the antenatal X-ray examinations of the mothers. The results of Dr. Stewart's investigation "show that there is a statistically significant number of children born of mothers given diagnostic x-rays prior to the children's birth who develop leukemia or cancer."¹⁰⁵ On the basis of these findings, it is obvious that it is particularly important to reduce the X-ray exposure to pregnant mothers to as low a level as possible. Thus, when the doctor knows that a patient is pregnant, he should not allow any X-rays¹⁰⁶ unless they are quite localized, as to an extremity, or unless there is preferential shielding of the womb,¹⁰⁷ or unless the condition is so critical as to

97 J. GITLIN & P. LAWRENCE, *POPULATION EXPOSURE TO X-RAYS U.S.* 1964, 105-06 (Public Health Service Pub. No. 1519).

98 For articles recommending the use of fast films and the proper methods of film development as a means of eliminating unnecessary radiation, see K. Z. Morgan, *supra* note 87, at 10-12; Brodeur & Seagle, *supra* note 52, at 319-20; Hodges, *supra* note 52, at 582; Stahl, *supra* note 52, at 520-21.

99 Scott, *supra* note 62, at 427.

100 *Id.*

101 Russell & Russell, *Radiation Hazards to the Embryo and Fetus*, 58 *RADIOLOGY* 369, 375 (1952).

102 *Id.*

103 *Id.*

104 K.Z. Morgan, *Dental X-Ray Exposures*, January 29-30, 1962, at 22 (presented at the Medical College of Virginia School of Dentistry, Richmond, Virginia).

105 J. SCHUBERT & R. LAPP, *supra* note 80, at 170.

106 Russell & Russell, *supra* note 101, at 375.

107 *Id.* Preferential shielding "has been achieved to a highly satisfactory degree by precision coning, precision centering, masking the area where the fetal head lies, and protecting the remainder of the fetus by a leaded apron placed over the maternal abdomen." Kendig, *Reduction of Fetal Irradiation in Pelvimetry*, 75 *RADIOLOGY* 608, 611 (1960).

warrant the calculated risk.¹⁰⁸ In many cases, however, the doctor does not know that the patient is pregnant. In fact, during that period when the fetus is most susceptible to radiation injury (two to four weeks after conception), most women are not yet aware that they are pregnant.¹⁰⁹ Thus, the chance of avoiding irradiation to the fetus during this period of greatest susceptibility to injury is frighteningly low.¹¹⁰ In order to overcome this danger of exposure to the fetus during the most critical stage of pregnancy, it has been proposed that exposures to the abdominal and pelvic regions of women in the childbearing age be limited, whenever possible, to the relatively safe interval of ten days following the beginning of the menstrual cycle.¹¹¹ K. Z. Morgan, Head of the Health Physics Division of Oak Ridge National Laboratory, recently evaluated this proposal in the following manner:

[A] big step forward was taken when the ICRP [International Commission on Radiation Protection] in 1962 made a recommendation cautioning members of the medical profession where possible without detriment to the health of the patient to limit x-ray diagnostic exposure to the pelvic and abdominal region of women in the childbearing age to the 10-day interval following the beginning of menstruation. It is difficult to obtain an accurate estimate of how many exposures to the embryo or foetus can be avoided each year if all members of the medical profession will give heed to these words of caution of the ICRP and conscientiously apply this principle. I believe the cautious and prudent application of this recommendation in the United States can prevent hundreds and perhaps thousands of children being born each year with mental and physical handicaps of varying degrees, the vast majority of which go undetected in our complex society. . . . Some doctors in the past — and even today — routinely advise or require x-ray examinations of all their pregnancy cases — a practice which I as a layman consider to be extremely unwise. . . . I believe any foetal dose delivered without a specific indicated medical need is too much. I hope in the near future the Public Health Service, the ICRP, NCRP and the medical associations will do what they can to discourage all unnecessary medical exposures to children at a time when they are most susceptible to radiation damage.¹¹²

The seriousness of this problem and the necessity of immediate action is indicated by the practice of doctors in some countries (such as Denmark) of performing an abortion if the woman has received doses of twenty or more rads to the pelvic or abdominal region.¹¹³

108 J. SCHUBERT & R. LAPP, *supra* note 80, at 179.

109 Russell & Russell, *supra* note 101, at 373.

110 "It was estimated that . . . [in 1955] over 2,500,000 women in the USA were exposed to X-rays from 5-80r in clinical diagnosis and it is anybody's guess as to how many thousand of those women were pregnant within the first three or four weeks." J. SCHUBERT & R. LAPP, *supra* note 80, at 258.

111 *Id.* at 168-71, 179; Hammer-Jacobsen, *Therapeutic Abortion on Account of X-Ray Examination During Pregnancy*, 6 DANISH MEDICAL BULLETIN 113, 120-21 (1959); Russell & Russell, *supra* note 101, at 373. *But see* Brown, *Radiation Control: Standardization Versus Freedom*, 82 RADIOLOGY 972, 974-76 (1964).

112 K.Z. Morgan, *Maximum Permissible Exposure to Ionizing Radiation*, April 13-15, 1966, at 9-10 (presented at the Conference on the Use of X-Rays in Medicine and Industry, Miami, Florida).

113 *See* Hammer-Jacobsen, *supra* note 111.

b. Fluoroscopy

The operating procedures in fluoroscopy which contribute to unnecessary radiation exposure are: failure to use adequate protective gloves and apron; failure to sufficiently use dark adaptation; use of the fluoroscope when films would adequately serve the diagnostic purpose; mass chest X-ray programs; failure to use gonadal shielding; and irradiation of the fetus.¹¹⁴

The use of adequate protective gloves and apron by the operator of a fluoroscope is absolutely necessary to keep his cumulative dose within safe limits. Yet radiation protection surveys have shown that not all doctors use such protective garments.¹¹⁵

When the fluoroscope operator's eyes are improperly adapted to the dark-room, he must increase the amount of radiation in order to sufficiently view the organ under diagnosis. Thus, by properly adapting his eyes to the dark, the operator may drastically reduce the radiation exposure to himself and the patient.¹¹⁶ Special red dark-adaptation goggles are available¹¹⁷ and all fluoroscope operators should be required to use them.

Because of the high radiation output during fluoroscopy, it has been recommended that "this procedure should be used only when absolutely necessary, especially since more accurate results may be obtained by other techniques with a smaller radiation dosage."¹¹⁸ P. C. Hodges has expressed a deep concern as to the irresponsible use of the fluoroscope:

In our own institution, like many others, fluoroscopes are scattered through chest clinics, cardiac clinics, surgical clinics, pediatrics clinics, and while I am sure that some of our colleagues who use them use them cautiously and wisely, I fear that many of the younger members of the staff use fluoroscopy as a sort of laying on of hands and find in dark goggles, aprons, and leaded gloves something of the prestige value that the medical student finds in his brand new head mirror. In the interest of the well-being of patients and staff, fluoroscopy of all sorts should be held to a minimum and that which is done should be done by radiologists.¹¹⁹

114 See Blatz, *supra* note 78, at 1387-88; Brodeur & Seagle, *Selecting Surveyors of X-Ray Equipment*, 79 PUB. HEALTH REP. 317, 319-20 (1964); Hodges, *Health Hazards in the Diagnostic Use of X-Rays*, 166 J.A.M.A. 577, 582-83 (1958); K.Z. Morgan, *Medical X-Ray Exposure*, 24 AM. INDUS. HYGIENE ASS'N J. 588, 594 (1963); Stahl, *X-Ray Protection Techniques*, 75 PUB. HEALTH REP. 513, 523-24 (1960).

115 See Appendix A, Medical Fluoroscopy Section *infra*.

116 Blatz, *supra* note 78, at 1388; Brodeur & Seagle, *supra* note 114, at 319-20; Hodges, *supra* note 114, at 582-83; Stahl, *supra* note 114, at 523.

117 See Blatz, *supra* note 78, at 1388; Stahl, *supra* note 114, at 523.

118 Corday & Jaffe, *Routine Cardiac Fluoroscopy—An Unnecessary Health Hazard*, 172 J.A.M.A. 1127 (1960). For an article recommending the use of films rather than fluoroscopy in chest examinations see Blatz, *supra* note 78, at 1387-88.

119 Hodges, *supra* note 114, at 583. The dosage involved in the use of fluoroscopy when not absolutely necessary is well illustrated by the following example given by Corday and Jaffe:

I have recently discussed this problem with a renowned diagnostician whose fingers had been badly burned through the use of fluoroscopy. Even though this authority has required skin grafting because of injury to his fingers from radiation, he continues to use fluoroscopy in his routine examinations because he does not have sufficient floor space to install an x-ray film unit. An x-ray film unit would reduce the amount of radiation to which this diagnostician would be exposed.

Corday & Jaffe, *supra* note 118.

A specific area in which the use of a fluoroscope can result in exceedingly high doses is that of mass chest X-ray programs. K. Z. Morgan, after a thorough study of the use of the fluoroscope in such programs, stated that

the dose from the use of the fluoroscope in these mass chest x-ray examinations can result in exceedingly high doses to other parts of the body such as to the eyes, skin and bone marrow. . . . No thorough survey has been made to determine the mean bone marrow dose from the mass chest x-ray programs in the U.S. Many spot checks have been made in which it was found that skin doses ranged from 20 mrem to 5000 mrem per chest x-ray. . . . Certainly it is reasonable to expect that no wise and responsible leaders of a community would support a mass chest x-ray program unless and until they had satisfactory evidence that there is a local need for such a survey and that the equipment will be operated in such a manner as not to expose the population to an excessive amount of unnecessary dose. They must be assured that the beam width is only that needed for a satisfactory chest radiogram and that the equipment, techniques and procedures used are such that the skin dose per x-ray will be much closer to 20 mrem than to 5000 mrem. Compliance with reasonable radiation protection standards can be determined only by the registration, inspection and calibration of the x-ray equipment used for these and other programs employing x-ray diagnosis and by insistence that this equipment be used only in accordance with instructions for its proper use. Only in exceptional circumstances (*e.g.*, in areas where there is a very high incidence of tuberculosis) should mass chest x-ray surveys include children.¹²⁰

The same considerations concerning the use of gonadal shielding and the utilization of operating techniques designed to protect the fetus discussed in relation to radiographic procedures¹²¹ apply to fluoroscopic procedures. In fact, the higher radiation output during fluoroscopy should prompt medical personnel to implement the safeguards previously mentioned in the radiographic section with even more immediacy and rigor.

The foregoing discussion of the use of X-rays in medical diagnostic examinations clearly indicates that the population of the United States is presently being exposed to unnecessary radiation. W. R. Stahl, and others, concluded from their experience that the successful application of the proper techniques concerning equipment changes and operating procedures on a wide scale would "reduce population gonadal exposure to one-half and perhaps to as little as one-fifth of present exposure."¹²² Likewise, K. Z. Morgan asserts that "there is little doubt that with better equipment and more skill and care in its use better radiological information would be obtained with less than 10% of the present population medical exposure in the United States."¹²³ This is a very serious indictment of the medical profession, and steps should be taken immediately to reduce the exposure in all X-ray examinations to an absolute minimum. It is submitted that the magnitude of the problem and the dangers involved in medical X-ray examinations are such that the police power of the

120 K.Z. Morgan, *supra* note 114, at 594.

121 See notes 91-113 *supra* and accompanying text.

122 Stahl, *supra* note 114, at 658.

123 K.Z. Morgan, *supra* note 112, at 12.

states should be invoked.¹²⁴ The X-ray equipment standards are sufficiently precise for the promulgation of binding regulations.¹²⁵ Some of the operating procedures, however, are so intertwined with medical discretion that only the suggestion of proper techniques would be appropriate.

B. Dental X-Ray Diagnosis

As in the case of medical X-rays, the radiation hazards associated with dental X-ray installations may be classified as those related to (1) the equipment and its accessories, and (2) the manner in which the equipment is used, *i.e.*, operating procedures.¹²⁶ A major distinction between medical and dental X-ray examination is that dental fluoroscopic examinations serve no useful purpose whatsoever and are universally forbidden by dental authorities.¹²⁷ Thus, the fluoroscope will not be discussed in regard to dental X-ray examinations.

1. X-Ray Equipment

The standards for protection against unnecessary radiation hazards in dental X-ray equipment and its accessories have been quite clearly expressed by the NCRP in a series of handbooks, the latest of which is the previously mentioned Handbook 76.¹²⁸ It will be assumed throughout this discussion that failure to comply with these standards leads to unnecessary radiation exposure.

The deficiencies in dental X-ray equipment that contribute to unnecessary radiation exposure are: inadequate beam collimation, use of a plastic pointer cone, inadequate filtration, use of mechanical timers, and an inadequate protective housing around the tube head.¹²⁹

Inadequate collimation or restriction of the X-ray beam results in radiation exposure to areas of the patient's body not under diagnostic study.

Large beams needlessly irradiate structures such as the lens of the eye, the thyroid gland, and contiguous structures in the neck and head, while contributing nothing of diagnostic value to the radiograph. Radiation of

124 The need for the invocation of the state police power will be more fully developed in Section IV of this Note, "Inadequacy of Judicial Remedies."

125 See Section V of this Note for a discussion of a Model Statute creating an agency with the power to issue binding regulations. Suggested regulations are set forth in Appendix C *infra*.

126 H. BLATZ, INTRODUCTION TO RADIOLOGICAL HEALTH 256 (1964).

127 The American Dental Association asserts in its Guide to Dental Materials that: The use of intraoral fluoroscopic 'mirrors' is considered to be irrational and dangerous. It can only result in harm to the operator. . . . Moreover, fluoroscopy requires extensive irradiation of the patient in order to observe a transient picture of a condition that can be recorded permanently on film at a fraction of the exposure employed. Intraoral fluoroscopy violates the fundamental principles of judicious radiation hygiene. Such devices are ineligible for display at Association meetings or for advertising in periodicals of the American Dental Association. AMERICAN DENTAL ASS'N, GUIDE TO DENTAL MATERIALS 103 (3d ed. 1966).

128 HANDBOOK 76, *supra* note 49, at 16-17.

129 See AMERICAN DENTAL ASS'N, *supra* note 127, at 99-101; K.Z. Morgan, Radiation Hazards in Metropolitan Areas, June, 1964, at 29 (submitted as a paper to the World Health Organization, Geneva, Switzerland); Alcox, Downs, Jacoe, *Colorado Dental X-Ray Machine Survey, 1961-April 1965*, 7 RADIOLOGICAL HEALTH DATA AND REPORTS 319-25 (1966); Menczer, *The Open-Ended Metal Column for the Dental X-ray Machine*, 73 J.A.D.A. 1083 (1966); TIME, Dec. 9, 1966, at 72.

the lens of the eye and the thyroid gland may be a contributing factor to cataractogenesis and thyroid tumorigenesis. Collimation of the primary beam to the area of diagnostic concern also leads to better defined radiographs by diminishing backscatter radiation.¹³⁰ (Footnote omitted.)

Elimination of this unnecessary radiation exposure to patients has been called for by many authorities on X-ray protection,¹³¹ yet inadequate collimation of the X-ray beam still exists in many dental offices.¹³²

A further reduction in unnecessary radiation exposure to the patient can be achieved by the replacement of the plastic pointer cone with an open-ended shielded cone.¹³³

It has been demonstrated that gonadal exposure from dental radiography can be reduced at least 50 percent if the plastic pointer cone is replaced by an open-ended shielded device. Such a device will reduce the exposure to the rest of the patient's body and the operator's body to X-radiation. . . .

The open-ended metal column also will eliminate penumbra, a halo-like effect of radiation around the primary beam, that has no usefulness in dental radiography and exposes the patient unnecessarily. . . .¹³⁴

The plastic pointer cone makes aiming of the X-ray beam easier, but this is hardly a sufficient justification for the radiation hazard involved in its use.

In order to meet accepted radiation protection standards the dental X-ray machine must be properly filtered to weed out the soft X-rays which do not reach the film and thus produce unnecessary radiation to the patient.¹³⁵ Even though some filtration of the useful beam is inherent in the structural elements of the tube head, it is usually necessary to add aluminum disks for additional filtration. The insertion of aluminum disks into the tube head is a simple and inexpensive process. Nevertheless, radiation protection surveys of dental offices indicate that a substantial number of X-ray machines do not have adequate filtration.¹³⁶

Collimation of the useful beam, use of a lead-lined open cone, and adequate filtration can reduce the radiation exposure to the patient's skin by 62%, eyes by 67%, thyroid gland by 71%, spinal cord area by 68%, and pituitary gland by 77%.¹³⁷ This reduction in radiation exposure to the patient warrants the

130 Alcox, Downs, Jacoe, *supra* note 129, at 320.

131 See AMERICAN DENTAL ASS'N, *supra* note 127, at 99-101; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 319-25; Menczer, *supra* note 129, at 1083-84; TIME, *supra* note 129.

132 See Appendix A, Dental Radiography Section, Collimation subdivision *infra*.

133 See AMERICAN DENTAL ASS'N, *supra* note 127, at 99-101; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 321, 323; Menczer, *supra* note 129, at 1083-84; TIME, *supra* note 129, at 73.

134 Menczer, *supra* note 129, at 1084. See AMERICAN DENTAL ASS'N, *supra* note 127, at 100.

135 See AMERICAN DENTAL ASS'N, *supra* note 127, at 99-101; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 319-25; Menczer, *supra* note 129, at 1083-84; TIME, *supra* note 129, at 73. The soft X-rays do not have sufficient penetrating ability to pass through the patient and expose the film. Thus, the soft-rays are absorbed by the patient and contribute nothing to the diagnostic quality of the radiograph.

136 See Appendix A, Dental Radiography Section, Filtration subdivision *infra*.

137 K. Winkler, Laboratory Evaluation of a Dental X-Ray Unit Collimating Device, May 22, 1964, (Report of the Public Health Service, Division of Radiological Health).

immediate implementation of the above-mentioned corrective measures by all dentists. The dentist seeking maximum radiation protection for his patients can add the "Medwedeff device"¹³⁸ to his present equipment. The Medwedeff device results in an additional reduction to that mentioned above of 28% to the skin, 31% to the eyes, 26% to the thyroid gland, 26% to the spinal cord area, and 18% to the pituitary gland.¹³⁹

Other X-ray equipment deficiencies which lead to unnecessary radiation in dental X-ray examinations are an inadequate protective housing around the tube head,¹⁴⁰ and a mechanical rather than electronic timer.¹⁴¹ An electronic timer is a prerequisite to the use of high-speed X-ray films, and thus an absolute necessity in any effective radiation protection program.¹⁴²

2. Operating Procedures

The operating procedures in dental X-ray examinations which contribute to unnecessary radiation exposure are: use of slow film, improper film development, the patient or operator holding the film, failure to provide local shielding for the patient, no personnel monitoring program, and failure to analyze personnel shielding and positioning.¹⁴³

According to the American Dental Association, "the use of high-speed films is the most effective means for reducing the radiation exposure of the patient."¹⁴⁴ High-speed film can reduce the exposure time from the two or three seconds needed for slow-speed films to a fraction of a second. This reduction in the exposure time naturally permits a large reduction in the total exposure of the patient. Elimination of the unnecessary radiation exposure inherent in the use of slow-speed films has been demanded by authorities on X-ray protection,¹⁴⁵ yet many dentists persist in the use of such films.¹⁴⁶

The manner in which the X-ray film is processed plays an important role in the reduction of unnecessary radiation exposure to the patient. The most common error in film processing is the overexposure and underdevelopment of the X-ray film.¹⁴⁷ Prolonging the development time permits the exposure time to be reduced. For example, "if the time of development is increased from three

138 The "Medwedeff device" was developed by Dr. Fred M. Medwedeff of Nashville, Tennessee. This device utilizes a stainless-steel plate in conjunction with a rectangular window to accomplish collimation. In addition, it has a steel bracket to hold the film exactly in the proper position, without subjecting the patient's hand to radiation.

139 K. Winkler, *supra* note 137.

140 AMERICAN DENTAL ASS'N, *supra* note 127, at 100-01; K.Z. Morgan, *supra* note 129, at 29.

141 See AMERICAN DENTAL ASS'N, *supra* note 127, at 99-101; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 321, 323; Menczer, *supra* note 129, at 1084; TIME, *supra* note 129, at 73.

142 See notes 144-46 *infra* and accompanying text.

143 See AMERICAN DENTAL ASS'N, *supra* note 127, at 101-03; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 319-25; Menczer, *supra* note 129, at 1084; TIME, *supra* note 129, at 73.

144 AMERICAN DENTAL ASS'N, *supra* note 127, at 100.

145 See AMERICAN DENTAL ASS'N, *supra* note 127, at 100-01; K.Z. Morgan, *supra* note 129, at 29; Alcox, Downs, Jacoe, *supra* note 129, at 319-25; Menczer, *supra* note 129, at 1084; TIME, *supra* note 129, at 73.

146 See Appendix A, Dental Radiography Section, Film Speed subdivision *infra*.

147 Alcox, Downs, Jacoe, *supra* note 129, at 323.

to five or six minutes, the radiation exposure may be reduced about 25 per cent.¹⁴⁸ Other film-processing techniques which can reduce the radiation exposure to the patient are: using fresh chemicals, a thermometer and a timer rather than the "sight" method;¹⁴⁹ and eliminating improper illumination or light leaks in the darkroom which will fog the film.¹⁵⁰

Another way in which unnecessary radiation exposure can be eliminated is to prohibit the dentist or patient from holding the film in place during the X-ray examination.¹⁵¹ The need for corrective measures in this regard is sufficiently demonstrated by the following comments of the American Dental Association:

The literature is replete with accounts of severe and sometimes fatal injuries to operating personnel as a result of such practices [holding X-ray film in place]. Neoplastic changes are a common occurrence; the development of the neoplasms is usually delayed for various periods depending upon the frequency of the exposure. Yet, the Bureau of Economic Research and Statistics reported that in spite of all the warnings almost 10 per cent of the dentists who replied to the question, "Do you hold the film in the patient's mouth while the x-ray is being taken?", stated that they held film occasionally or frequently, and almost 2 per cent of the dentists surveyed had lesions caused by such practices.¹⁵²

Because of the frequency of exposure, the hazard to the dentist is much greater than that to the patient from holding the film in place. This, however, is not a valid reason for having the patient hold the film because the use of film holders or bitewing film eliminates the need for anyone to hold it.

Another procedure which dentists can use to reduce the radiation exposure to patients during dental X-ray examinations is to provide the patient with a protective lead apron.¹⁵³ The importance of this procedure is illustrated by the U.S. Public Health Service's recommendation that *every* dental patient be protected with such aprons.¹⁵⁴ Yet radiation-protection surveys indicate that the vast majority of the dentists do not provide lead shielding for their patients.¹⁵⁵

The considerations concerning the utilization of personnel monitoring, shielding and positioning in dental X-ray installations are the same as those for medical X-ray installations.¹⁵⁶ As pointed out previously, the benefits in radiation protection which can be derived from personnel monitoring, shielding and

148 AMERICAN DENTAL ASS'N, *supra* note 127, at 102.

149 K.Z. Morgan, *supra* note 129, at 29.

150 AMERICAN DENTAL ASS'N, *supra* note 127, at 102.

151 *Id.* at 102-03; K.Z. Morgan, *supra* note 129, at 29; Menczer, *supra* note 129, at 1084.

152 AMERICAN DENTAL ASS'N, *supra* note 127, at 103.

153 For articles advocating the use of protective lead aprons in dental X-ray examinations see note 91 *supra*.

154 TIME, *supra* note 129, at 73. The American Academy of Oral Roentgenology recommends the use of lead aprons "as a prudent measure to use with children and pregnant women, and with other patients if the anticipated gonadal exposure is much larger than the gonadal exposure resulting from daily exposure to natural background radiation." AMERICAN DENTAL ASS'N, *supra* note 127, at 101. See also Fischman & Dunning, *Patient Protection in Dental Roentgenology*, 3 DENTAL PROGRESS 28-29 (1962) in which the authors describe a shield that reduces the gonadal exposure by 99-100 percent.

155 See Appendix A, Dental Radiography Section, Patient Shielding subdivision *infra*.

156 See notes 87-90 *supra* and accompanying text.

positioning are substantial.¹⁵⁷ Nevertheless, many dental X-ray installations do not employ such procedures.¹⁵⁸

The preceding discussion of the use of X-rays in dental diagnostic examinations clearly supports the proposition that the population of the United States is presently being exposed to unnecessary radiation. *Time* magazine, in a comment on X-ray safety in dentistry, stated that

At the American Dental Association convention in Dallas, there was disagreement over something that patients have long taken for granted: the safety of dental X rays. Although the A.D.A. has been encouraging the use of safer X-ray machines for years, many devices of antique design still adorn countless offices.¹⁵⁹

Dr. Fred M. Medwedeff deplores the use of such antique equipment in dental offices by asserting that "dental radiography as practiced today in the average office, exposes the patient to five to 30 times as much radiation as is necessary for the information being sought."¹⁶⁰ The corrective measures previously discussed which would reduce the radiation exposure to a minimum are dismissed by some dentists as too costly and unnecessary,¹⁶¹ while others are not even aware of the radiation hazard.¹⁶² This is a very serious indictment of the dental profession, and steps should be taken immediately to reduce the exposure in all X-ray examinations to an absolute minimum. It is submitted that the magnitude of the problem and the hazards involved in dental X-ray examinations are such that the police power of the states should be invoked.¹⁶³

IV. Inadequacy of Judicial Remedies

Having established that unnecessary radiation exists in the medical and dental use of X-rays, and that this radiation can result in long-term injurious effects, the obvious question becomes: What relief does our judicial system afford to those who have received unnecessary radiation? The purpose of this section is to demonstrate that the judicial process is totally incapable of dealing with radiation-induced effects of medical and dental X-rays, and that the means of combating unnecessary exposure will have to be sought elsewhere.

The following appraisal of the judicial remedies available for unnecessary radiation exposure is restricted solely to the long-range biological effects of low-level radiation exposure, and is not meant to cover the acute and readily dis-

157 *Id.* See also Alcox, Downs, Jacoe, *supra* note 129, at 323-24.

158 See Appendix A, Dental Radiography Section, Personnel Monitoring & Personnel Shielding subdivisions *infra*.

159 *TIME*, *supra* note 129.

160 Letter from Dr. Fred M. Medwedeff to James H. Seckinger, Feb. 9, 1967, on file with the *Notre Dame Lawyer*.

161 *TIME*, *supra* note 129, at 73.

162 Dr. Medwedeff summarizes the purpose of this Note when he states that "[i]f the profession and the public knew the facts, the situation would correct itself rather rapidly." Letter from Dr. Fred M. Medwedeff to James H. Seckinger, Feb. 20, 1967, on file with the *Notre Dame Lawyer*.

163 The need for the invocation of the police power will be more fully developed in the next section of this Note, "Inadequacy of Judicial Remedies."

cernible radiation injuries of higher levels of dosage. These latter radiation injuries, such as radiation burns, do not constitute a widespread problem in the medical and dental field, and when they do occur the judicial process is quite capable of adequately compensating the victim.¹⁶⁴

A. Difficulty of Discovering Radiation-Induced Injuries and Relating Them to Previous X-Ray Exposures

The radiation-induced injuries that are possible from unnecessary radiation exposure are: (1) the induction of malignancies such as leukemia, epithelioma, bone tumors, depilation, and dermatitis; (2) local effects on tissues; (3) effects on growth and development; (4) shortening of life span; (5) increased susceptibility to disease; (6) decreased fertility; and (7) genetic damage.¹⁶⁵ These radiation-induced injuries have two characteristics which greatly complicate the invocation of the judicial process. First of all, the latent period between the time an injurious dose of radiation is received and the manifestation of physiological damage may be several years or even several generations.¹⁶⁶ In addition, such injurious effects do not differ in a qualitative manner from diseases and abnormalities normally present in the population.¹⁶⁷ Therefore, an individual who has received unnecessary radiation from medical and dental X-rays will probably never discover the adverse effects of such irradiation;¹⁶⁸ and if he does, he would most likely fail to relate it to an X-ray he received many years previously. Thus, in most cases of radiation-induced injury from medical and dental X-rays, the judicial process would not even be given the opportunity to cope with the problem of unnecessary radiation and the resulting injurious effects.

B. Ability of the Judicial Process to Cope With Radiation-Induced Injuries

Assuming that an individual who has received unnecessary radiation from medical or dental X-rays discovers an injury resulting from such irradiation and asserts that it was caused by the X-rays he received many years previously, what relief can he expect to receive from our judicial process? The judicial barriers of the statute of limitations, causation-in-fact, and proof of negligence confront him immediately and present formidable obstacles.¹⁶⁹

164 See notes 8-9 *supra* and accompanying text.

165 See Section II of this Note, "Latent Radiation Injuries: An Unseen Danger," in particular, notes 16-19, 31-32 *supra* and accompanying text.

166 Powell, *Effects of Radiation on Man*, 12 VAND. L. REV. 81, 85, 91 (1958). See Estep, *Radiation Injuries and Statistics: The Need for a New Approach to Injury Litigation*, 59 MICH. L. REV. 259, 262 (1960). See also notes 11-12 *supra* and accompanying text.

167 *Id.*

168 The latent period of from several years to several generations makes it highly unlikely that an individual will discover the adverse effects of radiation. Furthermore, the average individual would not become aware of effects on growth and development, shortening of life span, increased susceptibility to disease, decreased fertility, and genetic damage.

169 Estep, *supra* note 166, at 262; Forgotson, *Causation-in-Fact in Radiation Injuries*, 39 TEXAS L. REV. 189 (1960). See J. SCHUBERT & R. LAPP, *RADIATION: WHAT IT IS AND HOW IT AFFECTS YOU* 202 (1963).

1. Statute of Limitations

The majority of the state decisions designate the time when the negligent act or some damage occurs as the point when the cause of action accrues and the statute of limitations begins to run.¹⁷⁰ Since the statutory period for actions grounded in negligence is generally six years or less, the statute usually will have run in these states before the radiation-induced injury manifests itself.¹⁷¹ The obvious injustice of this interpretation of the action's point of accrual has resulted in a number of jurisdictions ruling that the limitations period will be measured from the date on which the plaintiff has in fact discovered his injury, or by the exercise of reasonable diligence, should have discovered it.¹⁷²

The oppressive effect of the statute of limitations on tort cases involving radiation-induced injuries is exemplified by S. D. Estep and T. W. Van Dyke's statement:

Application of existing statutory periods and the usual interpretation of when a cause of action accrues will make it difficult, if not impossible, to recover on many meritorious claims arising from delayed manifestation injuries. Even in those states in which the judiciary has employed the concept of notice of an injury to the claimant as a prerequisite for accrual, the solution is not entirely adequate. Not only is there a lack of uniformity in the decisions as to what constitutes sufficient notice, but . . . statutory tolling provisions and judicially-created rules suspending the limitation period can be invoked only in particular situations and cannot be relied upon to achieve a just solution in many radiation cases.¹⁷³

Estep and Van Dyke have concluded that "[t]o be reasonable, a limitation statute applicable to radiation injuries should provide an over-all period of thirty years from the date of exposure."¹⁷⁴ This suggestion has been adopted by the Council of State Governments in their Model Act for Statutes of Limitation in Ionizing Radiation Injury Cases.¹⁷⁵ However, even if this Model Act should be adopted in every state, an individual seeking recovery for a radiation-induced injury will have to overcome the tort principles of causation-in-fact and proof of negligence, an onerous task indeed.

2. Causation-in-Fact

A fundamental doctrine in the law of torts is that no man is liable for an

¹⁷⁰ Estep & Van Dyke, *Radiation Injuries: Statute of Limitations Inadequacies in Tort Cases*, 62 MICH. L. REV. 753, 756-57 (1964); see W. PROSSER, *LAW OF TORTS* § 30, at 147 (3d ed. 1964).

¹⁷¹ The latent period between the time an injurious dose of radiation is received and the manifestation of physiological damage may be several years, or several generations. See note 166 *supra* and accompanying text.

¹⁷² W. PROSSER, *supra* note 170, § 30, at 147-48. "The major impetus in this development came from the decision in *Urie v. Thompson*, wherein the Supreme Court held that the plaintiff's cause of action accrued when the injurious consequences of defendant's negligence became manifest." Estep & Van Dyke, *supra* note 170, at 764-65.

¹⁷³ Estep & Van Dyke, *supra* note 170, at 789.

¹⁷⁴ *Id.* at 790.

¹⁷⁵ The Council of State Governments, *Statutes of Limitation in Ionizing Radiation Injury Cases*, 26 SUGGESTED STATE LEGISLATION A-68 to A-70 (1967).

injury to another unless he has caused it.¹⁷⁶ Thus it is apparent that proof of causation-in-fact lies at the very heart of the plaintiff's case. The principal test of causation-in-fact is the "but for" test.¹⁷⁷ The essence of this test is that an injury is in fact caused by the defendant if it would not have happened but for the defendant's negligence.¹⁷⁸

The "but for" test presents a formidable, if not insurmountable, obstacle to a plaintiff seeking to recover for a radiation-induced injury. Although scientists agree that the plaintiff's injury can be caused by radiation, the plaintiff must prove that the particular radiation exposure in question more likely than not caused his injury.¹⁷⁹ Satisfying this burden of proof becomes extremely difficult in light of the characteristics of radiation-induced injuries. A radiation-induced injury may not manifest itself until several years or even several generations after the radiation exposure.¹⁸⁰ This latent quality of radiation-induced injuries leads to speculation and uncertainty concerning the actual cause of such injuries, an aspect hardly conducive to proving causation-in-fact. Secondly, radiation-induced injuries are nonspecific, that is, they are similar to diseases and abnormalities which exist in the population even without exposure to man-made radiation.¹⁸¹ This characteristic makes it almost impossible to prove that the plaintiff's injury would not have happened but for a negligent exposure. Thirdly, a radiation-induced injury can result from a single exposure or from a series of individual exposures received from the same or different sources over an extended period of time.¹⁸² This attribute of radiation-induced injuries presents obvious difficulties in proving causation-in-fact in a particular case. Finally, radiation-induced effects, in general, are a probability phenomenon.¹⁸³ "Although they can be demonstrated on a statistically significant basis with a sufficiently large population group, the presence or absence of these effects in any given individual may be impossible to establish."¹⁸⁴ Thus, it is apparent that, under the existing rules concerning proof of causation-in-fact, an individual cannot recover for a radiation-induced injury.¹⁸⁵

3. Proof of Negligence

Negligence has been defined as conduct "which falls below the *standard* established by law for the protection of others against unreasonably great risk of harm."¹⁸⁶ (Emphasis added.) The standard imposed is an external one,

176 2 F. HARPER & F. JAMES, *THE LAW OF TORTS* § 20.2 (1956); W. PROSSER, *supra* note 170, § 44, at 240; 2 RESTATEMENT (SECOND) OF TORTS § 430 (1965).

177 2 F. HARPER & F. JAMES, *supra* note 176, § 20.2; W. PROSSER, *supra* note 170, § 41, at 242; 2 RESTATEMENT (SECOND) OF TORTS § 431 (1965).

178 *Id.*

179 See Prosser, *supra* note 170, § 38, at 212; Forgotson, *supra* note 169, at 190.

180 See note 166 *supra* and accompanying text.

181 See note 167 *supra* and accompanying text. See also J. SCHUBERT & R. LAPP, *supra* note 169, at 209.

182 Powell, *supra* note 166, at 91.

183 Estep, *supra* note 166, at 262; O'Toole, *Radiation, Causation, and Compensation*, 54 *Geo. L.J.* 751, 767 (1966); see *NAS REP.* at 16.

184 Powell, *supra* note 166, at 91.

185 See generally Estep & Forgotson, *Legal Liability for Genetic Injuries from Radiation*, 24 *LA. L. REV.* 1, 36-47 (1963).

186 2 RESTATEMENT (SECOND) OF TORTS § 282 (1965).

“based upon what society demands of the individual, rather than upon his own notions of what is proper.”¹⁸⁷ The standard of care required of doctors and dentists is that they exercise reasonable care and have the skill and knowledge commonly possessed by members of the profession in good standing.¹⁸⁸ The courts have uniformly held that “juries composed of laymen are normally incompetent to pass judgment on questions of medical science or technique . . . [and] that there can be no finding of negligence in the absence of expert testimony to support it.”¹⁸⁹ The well-known reluctance of doctors to testify against one another may make it difficult, if not impossible, for a plaintiff who seeks to recover for a radiation-induced injury to obtain the expert testimony necessary to avoid a directed verdict.¹⁹⁰ Even if the plaintiff does procure such expert testimony he will undoubtedly be confronted with opposing expert testimony that the deficiencies in X-ray equipment and operating procedures complained of are so widespread in the medical or dental profession that such behavior could not be below the skill and knowledge common to the profession.¹⁹¹ The probability of the plaintiff overcoming all the defenses available to doctors or dentists is slight.

From the foregoing discussion of the statute of limitations, causation-in-fact, and proof of negligence, it is evident that the judicial process is totally incapable of dealing with the radiation-induced effects of medical and dental X-rays, and that the means of combating unnecessary exposure in medical and dental X-rays will have to be sought elsewhere.

V. Elimination of Unnecessary Radiation Exposure By State Legislative and Administrative Action

It is submitted that the most effective way to eliminate unnecessary radiation exposure in the medical and dental use of X-rays is the establishment of a

187 W. PROSSER, *supra* note 170, § 31, at 149.

188 See W. PROSSER, *supra* note 170, § 32, at 164 & nn.18-20, 165 & n.33.

189 *Id.* at 167 & n.44.

190 *Id.* at 167. This point is well illustrated by the advice which Dr. Trostler, known as an expert advisor on radiation injury, gave to a young doctor. “Just about ten years ago, word reached me that a bright, keen young radiologist in Central Illinois was about to arrange to testify against one of his competitors, in a roentgen dermatitis malpractice suit.” Dr. Trostler explained that the young doctor had asked him for advice on testimony, whereupon he replied:

I take it that you are asking this information for the purpose of helping the defendant in this case, as I feel sure that you think too much of your standing in the various societies to even consider appearing against any regular physician in a malpractice suit. We cannot be too careful about this, as we do not know how soon we may have to have similar aid from our fellows.

I have had numerous opportunities to appear as witness against other physicians, being offered large fees to do it, but have refused because of reasons too numerous to mention. I have no doubt that many other men of reputation and standing have had the same experience.

In his discussion of this case, Dr. Trostler concluded, “It is scarcely necessary to say that the bright young radiologist, to whom the foregoing letter was written, did not testify in the suit mentioned. In the absence of any medical witness . . . the trial judge directed the jury to bring in a verdict in favor of the physician defendant.” Trostler, *Some Lawsuits I Have Met and Some of the Lessons to be Learned From Them*, 25 RADIOLOGY 329, 332-33 (1935).

191 The plaintiff will not be able to counter this assertion of the custom of the profession with *The T. J. Hooper* rationale because the standard of care for doctors and dentists is the custom of their profession. See W. PROSSER, *supra* note 170, § 32, at 167-68.

comprehensive state radiation protection program through state legislative action. To be fully effective, such a program would have to provide for the promulgation and enforcement of regulations designed to eliminate all the deficiencies in X-ray equipment and operating procedures.¹⁹²

This Note proposes a model radiation protection statute and code of regulations which are set forth in Appendices B and C, respectively. The Model Statute and Regulations are expressly limited to the problems of radiation exposure in the healing arts. This approach was taken because radiation protection in the healing arts is an important, but extremely neglected area of legislative concern. Many states have statutes protecting against the hazards of radiation exposure in the atomic energy industry, *i.e.*, nuclear reactors and radioisotopes; but few, if any, include provisions designed to protect the public from the hazards of radiation exposure from the use of X-rays in the healing arts.¹⁹³ The protection afforded by such statutes is highly questionable in light of the fact that the use of X-rays in the healing arts accounts for an estimated ninety-six percent of all man-made radiation to which the population is exposed.¹⁹⁴ Thus, any state genuinely interested in reducing the population exposure to ionizing radiation must devote most of its attention to the use of X-rays in the healing arts.¹⁹⁵ By limiting the proposed Model Statute and Regulations to only the healing arts, this Note hopes to place the emphasis of a state radiation protection program where it rightfully belongs.

The proposed Model Statute is entitled: An Act Establishing a Commission on Radiation Protection for the Healing Arts and Providing for the Regulation and Compulsory Periodic Inspection of X-Ray Installations Employed in the Healing Arts. The policy of this Model Statute is set forth in section 1 in which it is stated that:

It is the policy of the State of _____, in furtherance of its responsibility to protect the public health and safety, to institute and maintain a regulatory program for sources of X-rays employed in the healing arts and thereby provide for the minimum of radiation exposure compatible with current scientific knowledge and techniques.¹⁹⁶

As pointed out in Section III of this Note,¹⁹⁷ the principal sources of unnecessary radiation exposure in the healing arts are the deficiencies in both X-ray equipment and operating procedures. Accordingly, the Model Statute provides for:

192 See Section III of this Note, "Unnecessary Radiation in Medical and Dental X-Ray Diagnosis," for a discussion of the deficiencies in the X-ray equipment and operating procedures.

193 See note 7 *supra* and accompanying text. The research for the statute did not disclose a single state statute which included provisions expressly designed to regulate the use of X-rays in the healing arts, but many were found that expressly excluded the healing arts from the scope of the statute.

194 Baumgartner & Blatz, *Control of Common Radiation Hazards in New York City*, 76 PUB. HEALTH REP. 583, 585 (1961). See Gitlin, Hayman, Proctor, & Roney, *Field Trial of a System to Obtain Data on Population Exposure to X-rays*, 79 PUB. HEALTH REP. 185 (1964).

195 K. Z. Morgan, *Radiation Hazards in Metropolitan Areas*, June 1964, at 8, (submitted as a paper to the World Health Organization, Geneva, Switzerland).

196 The Model Statute, Appendix B *infra*.

197 See notes 47-163 *supra* and accompanying text.

“(a) A program of compulsory inspection of X-ray Installations employed in the healing arts; (b) A program to advise and inform users of such X-ray Installations of the safest and most efficient operating procedures.”¹⁹⁸

These programs can best be carried out by creating a Commission on Radiation Protection for the Healing Arts. Section 4(a) of the Model Statute creates the Commission and designates the membership of it.¹⁹⁹ The Commission is created as an integral part of the Department of Health²⁰⁰ because they both operate in the same general area, and communication and cooperation between them is desirable to avoid collision in policy and duplication of personnel and equipment. The membership of the Commission is set at seven, six to be appointed by the governor and one to be an ex-officio member. The appointment provision is designed to assure that the Commission will be composed of a fair representation of those most knowledgeable in the field of radiation protection.²⁰¹ The head of the Department of Health is designated as an ex-officio member of the Commission in order to further the cooperation between the Commission and the Department of Health and to provide the Commission with the benefits of his knowledge and experience.

Section 4(f) of the Model Statute provides for regular meetings of the Commission each year.²⁰² In adopting this statute, a state may wish to insert a provision enabling the Commission to call emergency meetings. The alternative to such a provision is that the calling of such emergency meetings be left to the discretion of the Commission under its power in section 4(e) to make its own procedural rules.

The powers and duties of the Commission are set forth in section 5 of the

198 Section 2 of the Model Statute, Appendix B *infra*. The need for such compulsory inspection of all X-ray installations is succinctly summarized by Dr. Russel Morgan in his statement that:

the removal of unsafe x-ray equipment from the medical scene involves the creation in the health department of a competent group of radiation physicists who are given authority to inspect on a systematic basis the various x-ray installations which are operated by the members of the healing arts in their region. Although certain groups of professional men and technicians may be more prone than others to employ unsafe apparatus, there is no group in medical practice today that is operating with equipment which is entirely satisfactory. In general, certified radiologists tend to be better than those who have received relatively little training in the use of x-ray equipment. However, an inspection program should include the apparatus of all practitioners of the healing arts regardless of background.

R. H. Morgan, *Radiation Hazards of Primary Concern to Public Health—Present Status and Outlook*, 53 AM. J. PUB. HEALTH 872, 876 (1963). Dr. Morgan also points out the need for a program of education for users of X-ray equipment:

The problem of preventing the careless or imprudent use of diagnostic x-ray equipment is much more difficult than preventing the use of unsafe apparatus. Here one deals with the working habits of the professional and the technician and since careless and imprudent use of radiation does not result in any immediate deleterious effect, the correction of undesirable habit patterns is extremely difficult. . . . If a full and comprehensive education program is undertaken and if instrumentation can be applied to medical x-ray equipment by which improper use can be ascertained by public health inspectors, one can anticipate a very sharp reduction in the radiation exposure to which the population currently is subjected from medical sources. *Id.* at 876-77.

199 The Model Statute, Appendix B *infra*.

200 See Baumgartner & Blatz, *supra* note 194.

201 Section 4(a) of the Model Statute, Appendix B *infra*. See K. Z. Morgan, *supra* note 195, at 19-20.

202 The Model Statute, Appendix B *infra*.

Model Statute. Subsection 5(a)(1) commands the Commission to "adopt, promulgate, amend, and repeal such rules and regulations for the use and maintenance of X-ray Installations as may be necessary or appropriate to implement the policy set forth in section 1."²⁰³ To aid the Commission in fulfilling this command, a Model Code of Regulations is set forth in Appendix C. The adoption and promulgation of the necessary rules and regulations does not, however, terminate the Commission's responsibility under subsection 5(a)(1). An extremely important part of subsection 5(a)(1) is its command to amend and repeal the rules and regulations as may be necessary to implement the policy of the act. This aspect of 5(a)(1) insists that the Commission keep the rules and regulations current by periodically modernizing them in accordance with scientific developments in the field of radiation protection.

Subsection 5(a)(2) commands the Commission to "cause to be inspected all X-ray Installations"²⁰⁴ for the purpose of ascertaining their state of compliance with the act and the rules and regulations in force pursuant to it. The inspection of all X-ray installations is absolutely necessary to effectuate the policy of the act, for the rules and regulations will be rendered meaningless without such inspections.²⁰⁵ Thus this subsection, making inspections mandatory, is the very heart of an effective radiation protection program.

In subsection 5(a)(3), it is proposed that the Commission "provide for the appointment and training of such Inspectors as may be necessary to conduct inspections."²⁰⁶ The problem immediately confronting the Commission under this subsection is the determination of the qualifications of those who will inspect the X-ray installations. In establishing these qualifications, a study conducted by Dr. A. E. Brodeur and E. F. Seagle is pertinent:

To determine the qualifications necessary for a surveyor [Inspector] we conducted a study in St. Louis, Mo., with the aid of the State Assistance Branch of the Division of Radiological Health, designed to demonstrate the public health effectiveness achieved by the use of different categories of surveyors of X-ray installations. For the study we selected a hospital, two offices of radiologists, two offices or clinics of group practitioners, and three offices of private general practitioners.

These installations were independently surveyed for safety factors by:

1. The physician. (How well is your equipment protected against unnecessary radiation? What about your techniques and processing?)

2. A certified radiation physicist.

3. A certified health physicist.

4. A Public Health Service demonstration team trained especially for this purpose.

5. Health department sanitarians with no radiation control background or formal training other than 2 weeks' experience with the PHS team.²⁰⁷

203 *Id.*

204 *Id.*

205 *See* K. Z. Morgan, *supra* note 195, at 22-23.

206 The Model Statute, Appendix B *infra*.

207 Brodeur & Seagle, *Selecting Surveyors of X-ray Equipment*, 79 PUB. HEALTH REP. 317, 319-20 (1964).

The results of the study²⁰⁸ in terms of cost and effectiveness were:

Surveyor	Cost per unit	Percent effectiveness
PHS demonstration team	\$13	95+
Sanitarian	7	90+
Certified health physicist	25	82
Certified radiation physicist	76	25
Practitioner	35	64

It is evident from this study that a health department person with a college degree, who has been trained by the Public Health Service, is sufficiently qualified to inspect X-ray installations.²⁰⁹ The utilization of such personnel would be desirable in light of the relatively low cost involved and their immediate availability in all areas. Even if certified radiation physicists and certified health physicists are available for inspections, they would be more effectively utilized as consultants in matters such as the calibration of X-ray units, the formulation of X-ray protection standards, and the supervision of the X-ray inspection program.²¹⁰

Subsection 5(a)(4) commands the Commission to "collect and disseminate information relating to the safety of X-ray Installations and the operation thereof."²¹¹ This subsection is inserted to stress the fact that one of the most important functions of the Commission is the education of the users of X-ray installations. It is often difficult for the users of X-ray installations to keep abreast of the many changing developments and methods in the field of radiation protection. This subsection makes it the Commission's duty to inform the users of these new developments.

In subsection 5(b)(1), the Commission is provided with the power to "charge a reasonable fee for each inspection of an X-ray Installation."²¹² This allows the state to make its inspection program self-sustaining rather than dependent for all or part of the cost through appropriations. Besides helping to finance the inspection program, this fee can also result in inspection being taken more seriously.²¹³ Furthermore, it should be noted that a fee for "each inspection" contemplates a fee for reinspection of an X-ray installation.

Subsection 5(b)(2) is a standard provision providing for a governmental body with the power to "accept, receive and administer grants or other funds or gifts from public and private agencies, including the Federal Government for the purpose of carrying out any of . . . [its] functions. . . ."²¹⁴ This subsection is

208 *Id.* at 322.

209 It is extremely important to note that the results of the study conducted by Brodeur and Seagle do not imply that trained health department personnel with only a college degree are better qualified as radiation experts than certified radiation and health physicists. In fact the effectiveness of the health department personnel demonstrated by this study is a direct result of the skills of the radiation and health physicists who directed the establishment of the criteria used in the study. *See* Brodeur & Seagle, *supra* note 207, at 323.

210 *Id.*

211 The Model Statute, Appendix B *infra*.

212 *Id.*

213 *See* Baumgartner & Blatz, *supra* note 194.

214 The Model Statute, Appendix B *infra*.

of special importance to a state radiation protection program because of the federal funds available for such programs,²¹⁵ and also because of the many types of aid available from the State Assistance Branch of the Public Health Service's Division of Radiological Health.²¹⁶

Since other agencies and groups, federal, state, and local, operate in the field of radiation protection, subsection 5(b)(3)²¹⁷ is inserted to stimulate co-operation between the Commission and these agencies and groups, thus avoiding needless duplication of efforts.

Section 6 of the Model Statute specifies the method of inspecting X-ray installations. Section 6(a) provides that: "Each X-ray Installation shall be inspected by an Inspector every [] years for the purpose of ascertaining the state of compliance with this Act and the rules and regulations in force pursuant thereof."²¹⁸ The frequency of such inspections is left to the discretion of the state. In determining the frequency, it should be borne in mind that after the initial inspection subsequent inspections will be less costly and time consuming. Another factor to consider in determining the frequency of such inspections is that new developments in X-ray equipment and operating procedures, mandating the promulgation of new rules and regulations, may militate for a relatively short period between inspections. However, once compliance with the rules and regulations has been achieved through the initial inspection, subsequent inspections may yield diminishing returns and thus lend support for a longer period between inspections.

In section 6(b), it is provided that such inspections, in addition to ascertaining the state of compliance of an X-ray installation,

shall include a radiation protection survey consisting of a physical survey of the arrangement and use of the equipment and measurements of the exposure rates under expected operating conditions, and an evaluation of the radiation hazards in and around an X-ray Installation with recommendations to the user as to the elimination of such hazards.²¹⁹

It should be noted that the term "recommendations" used in this subsection contemplates measures necessary to alleviate hazards not mandatory under the rules and regulations.

Section 6(c),²²⁰ concerning entry or access of an inspector to an X-ray installation, was inserted to insure that the policy of this act would not be

215 As a stimulant to . . . [State radiation control] efforts Congress has provided funds for making State Program Development Grants. An initial appropriation of \$1,500,000 was made for fiscal year 1963 in a one-for-one matching basis. A major objective of these grants is to enable each state to assemble basic professional and technical staff to deal with radiation control problems. Chadwick, *The Public Health Role in Controlling Radiation*, 55 AM. J. PUB. HEALTH 731, 737 (1965).

216 Miller, *Summary of State Dental Radiological Health Activities*, RADIOLOGICAL HEALTH DATA 41, 44-45 (1963).

217 The Model Statute, Appendix B *infra*.

218 *Id.* For a very good discussion of what an inspection should consist of in order to effectively and economically ascertain the state of compliance of an X-ray installation with this Act and the rules and regulations in force pursuant thereof, see Baumgartner & Blatz, *supra* note 194, at 586-87.

219 The Model Statute, Appendix B *infra*.

220 *Id.*

thwarted by individuals not wishing to comply with the act.²²¹ Section 6(d) provides that:

Upon completion of the inspection the Inspector shall report his findings in writing to the Commission and the owner of the X-ray Installation and the person in charge thereof. Should the inspection disclose failure to satisfy any requirement of the rules and regulations in force pursuant to this Act, the Inspector shall file an order with his report which shall:

- (1) set forth the specific violations;
- (2) explain the corrective measures including changes in equipment or operating procedures necessary for compliance with such rules and regulations;
- (3) set a date which, in the Inspector's judgment, provides sufficient time to complete such corrective measures; and give notice of re-inspection to occur on or shortly after this date.²²²

It is necessary that the Commission receive the inspector's reports and orders as they are a source of facts upon which the Commission may base any modification of the rules and regulations, or grant any waiver. Furthermore, it is necessary that the reports and orders be sent to the owner and user in order to put them on notice of the condition of the X-ray installation and any corrective measures they must take to achieve compliance. Section 6(e), in conjunction with sections 7 and 8, prevents an X-ray installation from being used if reinspection discloses that the corrective measures called for in the order issued under subsection 6(d) have not been fulfilled.²²³

The enforcement provisions are found in section 7. Section 7(a) states that:

Any Inspector who finds a violation of sections 6(c) and (e) shall furnish evidence of such violation to the [insert appropriate prosecuting attorney] who shall prosecute any person violating any of the provisions of this Act and the rules and regulations in force pursuant thereto.²²⁴

The removal of discretion from the prosecuting attorney is provided to insure compliance with the provisions of the statute. It is not believed that this will overly burden his office because the violator's knowledge that he will be prosecuted should assure compliance in most instances. Section 7(b) classifies the violation of any of the provisions of the statute, or the rules and regulations in force pursuant to it, as a misdemeanor and leaves the limits of the fine to the discretion of the state.²²⁵

Section 8 of the Model Statute gives the Commission the power to "institute injunctive proceedings in a court of competent jurisdiction for the enforcement of the provisions of this Act, and any such injunctive proceeding may be joined with the action provided in section 7."²²⁶ This provision permits the Commission to protect the public from anyone who continually refuses to comply with the

²²¹ *Id.* The necessity of this provision is illustrated by the comments of K. Z. Morgan, *supra* note 195, at 21-22.

²²² The Model Statute, Appendix B *infra*.

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.*

rules and regulations despite the penalties. The joinder of penalties and injunctive proceedings is allowed to avoid separate time consuming proceedings where the two would more efficiently be brought together.

Section 10 of the Model Statute provides that:

The rules and regulations appended to this Statute shall be in effect until amended or repealed by the Commission pursuant to its powers in section 5(a)(1). The exercise of the Commission's power in 5(a)(1) shall be in accordance with [cite state administrative procedure act].²²⁷

This manner of adopting the initial code of rules and regulations is chosen rather than leaving it to the Commission's discretion pursuant to section 5(a)(1) because of the crucial role the rules and regulations in Appendix C play in an effective radiation protection program. The adoption of the initial code of rules and regulations by the legislature not only focuses the Commission's (and the public's) attention on the importance of the rules and regulations in the radiation protection program, but encourages the Commission to seriously and thoughtfully review the entire regulatory scheme before exercising its powers of adoption, amendment, and repeal under section 5(a)(1). The requirement of section 10 that the exercise of the Commission's power under section 5(a)(1) be in compliance with the state administrative procedure act is a standard provision. If a state administrative procedure act does not provide for a hearing or opportunity for interested persons to present suggestions to the Commission when adopting, amending, or repealing rules and regulations, and the state feels such opportunity should be afforded, additional provisions providing for such a procedure should be enacted.

In addition to the proposed Model Statute, the states should also consider enacting legislature requiring that courses in health physics and radiation protection be included in the curriculum of all medical and dental schools, and that questions on these subjects be included on the state board examinations.²²⁸ The need for such legislation is illustrated by the fact that

more than 50% of the x-ray machines are in the possession of non-radiologists, many of them with little or no training in the use of these machines. Furthermore, many of the x-ray machines are operated by technicians and in some cases by secretaries who know little more than which buttons are to be pressed.²²⁹

In 1965, California became the first state to enact such legislation and it is hoped that the rest of the states will follow suit shortly.²³⁰

VI. Conclusion

The hazards involved in any unnecessary radiation exposure are clear.²³¹

227 *Id.* These rules and regulations are set forth in Appendix C of this Note.

228 Brown, *Radiation Control: Standardization Versus Freedom*, 82 *RADIOLOGY* 972, 973 (1964); Morgan, *supra* note 198, at 877.

229 K. Z. Morgan, *Radiation Protection, Past, Present and Projection*, Aug. 24-26, 1966, at 12 (presented at the Conference on Principles of Radiation Protection, Oak Ridge, Tennessee).

230 CAL. BUS. & PROF. §§ 2192, 2246, 2288, 2292 (Supp. 1966).

231 See Section II of this Note, "Latent Radiation Injuries: An Unseen Danger."

In light of such hazards, it is imperative that our society require all radiation exposure to be kept as low as possible. The means advocated in this Note for eliminating all the unnecessary radiation exposure currently existing in the medical and dental use of X-rays may be met by vociferous objections. It is anticipated that the crux of these objections will be the insistence that medical and dental X-ray equipment and operating procedures should not be governed by legislation, but that such equipment and operating procedures should be controlled by the physician, radiologist, or dentist who will, in his best judgment, do what he considers best for his patients. This objection would be well founded if medical personnel were experts in radiation physics, used the best techniques, and had the most modern equipment in perfect operating condition.²³² That medical personnel do not meet all these qualifications is evident from the discussion in Section III of this Note concerning the prevalence of unnecessary radiation exposure in the use of medical and dental X-rays.

The pressing need for adoption of the proposed Model Statute²³³ and Code of Regulations²³⁴ is illustrated by the fact that one can state without equivocation that the changes which would be brought about by such action would reduce radiation exposure to patients by some fifty to ninety-five percent.²³⁵ It is important to note that this reduction in radiation exposure can be accomplished without impairing the quality of the X-ray²³⁶ or the efficiency of the diagnostic examination.²³⁷

By posing various policy questions relating to unnecessary radiation exposure in the medical and dental use of X-rays, this Note hopes to stimulate the thinking of the Bar and the Legislature on these fundamental and largely ignored matters. These groups have very little time left in which to act if they are to avoid the charge, so often leveled at them, that the legal system badly lags behind developments in the other sciences.

*James H. Seckinger**

232 K. Z. Morgan, Dental X-Ray Exposures, Jan. 29-30, 1962, at 26-27 (presented at the Medical College of Virginia School of Dentistry).

233 See Appendix B *infra*.

234 See Appendix C *infra*.

235 Stahl, *X-Ray Protection Techniques*, 75 PUB. HEALTH REP. 513, 517 (1960). Scott estimates that such action would reduce radiation exposure to patients by 75 to 85 percent. Scott, *The Clinical Radiologist and the Problems of Radiation Hazards*, 170 J.A.M.A. 421, 424 (1959).

236 Stahl, *supra* note 235, at 517.

237 Scott, *supra* note 235, at 424. It is interesting to note that K. Z. Morgan asserts that this reduction can be accomplished "while at the same time *improving and enhancing* the quality of diagnostic information obtainable from medical radiograms." K. Z. Morgan, Maximum Permissible Exposure to Ionizing Radiation, April 13-15, 1966, at 10-11 (presented at the Conference on the Use of X-Rays in Medicine and Industry, Miami, Florida). (Emphasis added.)

* B.S. degree in physics, candidate for M.S. degree in physics, and A.E.C. Health Physics Fellow in 1964-65. The writer wishes to thank the Notre Dame Law School Student Legislative Bureau, in particular James A. Hancock and Christopher F. Carroll, for their invaluable aid in drafting the Model Statute.

APPENDIX A—(continued)

- A. E. SEAGLE, X-RAY EQUIPMENT SURVEY IN POLK COUNTY, FLORIDA, SEPTEMBER 1961-AUGUST 1963, 24-29 (Public Health Service Pub. No. 999-RH-8).
- B. OREGON, Stahl, Sullivan & Wagstaff, *Findings of a Survey of X-Ray Units*, 75 PUB. HEALTH REP. 652, 654 (1960). 1. Hospitals and clinics with radiologists, 2. Hospitals and clinics without radiologists, 3. Physicians and dentists other than radiologists.
- C. LOS ANGELES, Brodeur & Seagle, *Selecting Surveyors of X-ray Equipment*, 79 PUB. HEALTH REP. 317-18 (1964).
- D. NEW YORK CITY. *Id.* at 318.
- E. CHEMUNG COUNTY, NEW YORK, 77 PUB. HEALTH REP. 531 (1962).
- F. UTAH, Wheeler & Winn, *Utah Dental X-Ray Machine Survey, 1961-1963*, 5 RADIOLOGICAL HEALTH DATA 505 (1964).
- G. BALTIMORE, Prather, Farber & Chaney, *Medical X-Ray Units in the City of Baltimore: Findings of the 1963 Pilot Survey*, 5 RADIOLOGICAL HEALTH DATA 341, 342-43 (1964).
- H. CALIFORNIA, J. Nanus, Results of 476 X-Ray Surveys Recently Performed by Texas Radiation Control Program, Table 2 (unpublished report on file with the *Notre Dame Lawyer*).
- I. ERIE COUNTY, NEW YORK. *Id.*
- J. TEXAS.
- K. UNITED STATES (surpak survey). Miller, *The Dental Surpak Program and Results Through December 1963*, 6 RADIOLOGICAL HEALTH DATA 271 (1965). 1. 1960 2. 1961 3. 1962 4. 1963.
- L. UNITED STATES. J. GITLIN & P. LAWRENCE, POPULATION EXPOSURE TO X-RAYS U.S. 1964 106, 109, 112-15 (Public Health Service Pub. No. 1519).
- M. COLORADO. Alcox, Downs, Jacoe, *Colorado Dental X-Ray Machine Survey, 1961-April 1965*, 7 RADIOLOGICAL HEALTH DATA 319 (1966).
- a. Standard of 2.5 millimeters of aluminum equivalent.
 - b. Standard of 24 inches for chest and the diagnostic area for other procedures.
 - c. Standard of 2.5 millimeters of aluminum equivalent.
 - d. Standard of 12 inches.
 - e. Standard of 18 inches. This is recommended by the American College of Radiology.
 - f. Standard of 10R/minute.
 - g. Standard of 1.5 millimeters of aluminum equivalent.
 - h. Standard of 2 millimeters of aluminum equivalent.
 - i. Standard maximum diameter of 3 inches.
 - j. Standard maximum diameter of 2.75 inches. This is recommended by the American College of Radiology.

APPENDIX B

AN ACT ESTABLISHING A COMMISSION ON RADIATION PROTECTION FOR THE HEALING ARTS AND PROVIDING FOR THE REGULATION AND COMPULSORY PERIODIC INSPECTION OF X-RAY INSTALLATIONS EMPLOYED IN THE HEALING ARTS.*

Be it enacted [etc.]

- 1) Policy. It is the policy of the State of _____, in furtherance of its responsibility to protect the public health and safety, to institute and maintain a regulatory program for sources of X-rays employed in the healing arts and thereby provide for the minimum amount of radiation exposure compatible with current scientific knowledge and techniques.
- 2) Purpose. It is the purpose of this Act to effectuate the declared policy set forth in section 1 by providing for:
 - (a) A program of compulsory inspection of X-ray Installations employed in the healing arts;
 - (b) A program to advise and inform users of such X-ray Installations of the safest and most efficient operating procedures.¹
- 3) Definitions. As used in this Act:
 - (a) "Commission" means the Commission on Radiation Protection for the Healing Arts as hereafter created.
 - (b) "Commissioner" means a member of the Commission.
 - (c) "X-ray Installation" means any device employed in the Healing Arts emitting X-rays, with its associated equipment and space in which it is located, excluding those owned by the U.S. Government and its agencies.
 - (d) "Inspector" means a Commissioner or anyone authorized by the Commission to conduct inspections of X-ray Installations.
 - (e) "Healing Arts" means medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.
- 4) Commission on Radiation Protection for the Healing Arts.
 - (a) There is hereby created [in the Department of Health] a Commission on Radiation Protection for the Healing Arts. The membership of the Commission shall be composed of [7] Commissioners, [6] of whom shall be appointed by the Governor [with scientific training in one or more of the following fields: radiology, medicine, dentistry, radiation or health physics, or related sciences, with specialization in X-rays; provided that no more than two individuals shall be specialists in one of the above named fields]. The [Head of the Department of Health] shall be ex officio the [7th] member of the Commission.²
 - (b) The terms of the appointed members of the Commission shall be for [4] years except that of those first appointed, 2 shall be appointed for terms of 1 year, 2 for terms of 2 years, 1 for a term of 3 years, and 1 for a term of 4 years, which terms shall commence on [insert appropriate date]. Vacancies shall be filled for the unexpired term.
 - (c) When on the business of the Commission, the appointed members of the Commission shall be entitled to receive compensation at the rate of [] dollars per diem and shall be reimbursed for actual expenses incurred.
 - (d) The Commission shall select a chairman from its members.
 - (e) The Commission shall adopt rules and procedures for conducting its business.
 - (f) The Commission shall hold at least [] regular meetings a year.³

* This Model Statute was drafted in conjunction with the Notre Dame Law School Student Legislative Bureau. James A. Hancock and Christopher F. Carroll worked on the project for the Bureau.

1 See notes 199-201 *supra* and accompanying text.

2 See notes 203-05 *supra* and accompanying text.

3 See note 206 *supra* and accompanying text.

(g) The Commission may employ such personnel and procure such office space and facilities as may be necessary for the administration of this Act.

5) Powers and Duties.

(a) The Commission shall: (1) adopt, promulgate, amend, and repeal such rules and regulations for the use and maintenance of X-ray Installations as may be necessary or appropriate to implement the policy set forth in section 1,⁴ (2) cause to be inspected all X-ray Installations in accordance with the provisions in section 6,⁵ (3) provide for the appointment and training of such Inspectors as may be necessary to conduct inspections,⁶ and (4) collect and disseminate information relating to the safety of X-ray Installations and the operation thereof.⁷ (b) The Commission may: (1) charge a reasonable fee for each inspection of an X-ray Installation,⁸ (2) accept, receive and administer grants or other funds or gifts from public and private agencies, including the Federal Government, for the purpose of carrying out any of the functions of this Act,⁹ (3) advise, consult and cooperate with other agencies of the state, local governments, other states, the Federal Government, and interested persons or groups.¹⁰

6) Inspection and Radiation Protection Survey.

(a) Each X-ray Installation shall be inspected by an Inspector every [] years for the purpose of ascertaining the state of compliance with this Act and the rules and regulations in force pursuant thereof.¹¹

(b) Such inspection shall include a radiation protection survey consisting of a physical survey of the arrangement and use of the equipment and measurements of the exposure rates under expected operating conditions, and an evaluation of the radiation hazards in and around an X-ray Installation with recommendations to the user as to the elimination of such hazards.¹²

(c) No person shall refuse entry or access to any Inspector who requests entry for purposes of inspection, and who presents appropriate credentials; nor shall any person obstruct, hamper or interfere with any such inspection.¹³

(d) Upon completion of the inspection the Inspector shall report his findings in writing to the Commission and the owner of the X-ray Installation and the person in charge thereof. Should the inspection disclose failure to satisfy any requirement of the rules and regulations in force pursuant to this Act, the Inspector shall file an order with his report which shall:

(1) set forth the specific violations;

(2) explain the corrective measures including changes in equipment or operating procedures necessary for compliance with such rules and regulations;

(3) set a date which, in the Inspector's judgment, provides sufficient time to complete such corrective measures; and give notice of re-inspection to occur on or shortly after this date.¹⁴

(e) No person in charge of an X-ray Installation shall use or allow to be used any X-ray Installation without complying with the order in subsection (d).¹⁵

4 See note 207 *supra* and accompanying text.

5 See notes 208-09 *supra* and accompanying text.

6 See notes 210-14 *supra* and accompanying text.

7 See note 215 *supra* and accompanying text.

8 See notes 216-17 *supra* and accompanying text.

9 See notes 218-20 *supra* and accompanying text.

10 See note 221 *supra* and accompanying text.

11 See note 222 *supra* and accompanying text.

12 See note 223 *supra* and accompanying text.

13 See notes 224-25 *supra* and accompanying text.

14 See note 226 *supra* and accompanying text.

15 See note 227 *supra* and accompanying text.

7) Enforcement and Penalties.

(a) Any Inspector who finds a violation of sections 6(c) and (e) shall furnish evidence of such violation to the [insert appropriate prosecuting attorney] who shall prosecute any person violating any of the provisions of this Act and rules and regulations in force pursuant thereto.¹⁶

(b) It shall be a misdemeanor to violate the provisions of sections 6(c) and (e) and punishable by a fine of not less than [\$] nor more than [\$]. Each violation and each day of violation shall constitute a separate offense.¹⁷

8) Injunction by the Commission.

The Commission may institute injunctive proceedings in a court of competent jurisdiction for the enforcement of the provisions of this Act, and any such injunctive proceeding may be joined with the action provided in section 7.¹⁸

9) Injunction by Aggrieved Party.

Any person aggrieved by an order of an Inspector may institute injunctive proceedings in a court of competent jurisdiction. No court shall refuse to enforce the order of an Inspector unless it finds the order to be unreasonable, arbitrary and capricious.¹⁹

10) Rules and Regulations.

The rules and regulations appended to this Statute shall be in effect until amended or repealed by the Commission pursuant to its powers in section 5(a)(1). The exercise of the Commissioner's power in 5(a)(1) shall be in accordance with [cite state administrative procedure act].²⁰

11) Authorization of Appropriations. [Insert appropriate section.]

12) Severability. [Insert appropriate section.]

13) Repeal. [Insert appropriate section.]

14) Effective Date. [Insert appropriate date.]

16 See note 228 *supra* and accompanying text.

17 See note 229 *supra* and accompanying text.

18 See note 230 *supra* and accompanying text.

19 See note 231 *supra* and accompanying text.

20 See note 232 *supra* and accompanying text.

APPENDIX C

REGULATIONS GOVERNING THE USE OF X-RAYS IN THE HEALING ARTS¹

Part 1. General Provisions

(a) Scope

These regulations establish standards for the use of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.

(b) Waiver

The Commission may waive compliance with the specific requirements of these regulations for a machine or installation if (i) such compliance would require replacement or substantial modification of the machine or installation and (ii) the user demonstrates, to the Commission's satisfaction, achievement of radiation protection equivalent to that required by these regulations through other means.

(c) Use.

1.c.1. The user shall be responsible for assuring that all requirements of these regulations are met.

1.c.2. The user shall assure that all X-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.

1.c.3. The user shall provide written safety rules to the individuals operating X-ray equipment under his control, including any restrictions of the operating technique required for the safe operation of the particular X-ray apparatus, and require that the operators demonstrate familiarity with these rules and regulations.

Part 2. Definitions

[For pertinent definitions see HANDBOOK 76 at 1-4.]

Part 3. Inspections

(a) Inspection

3.a.1. Each X-Ray Installation shall be inspected by an Inspector for the purpose of ascertaining the state of compliance with these rules and regulations. This shall also be done after any change in the Installation which might produce a radiation hazard. In evaluating the results of the inspection, account should be taken of actual operating conditions, including workload, use factor, occupancy, and attenuation of the useful beam provided by patients and objects normally in the path of the useful beam.

3.a.2. - 3.a.6.

[See HANDBOOK 76, ¶¶ 4.1.b.-4.1.f., at 8.]

(b) Report of the Inspection

3.b.1. The Inspector shall report his findings in writing to the Commission, and

¹ The primary sources for this Code of Regulations were HANDBOOK 76, *supra* note 49 and DEPARTMENT OF THE ARMY AND AIR FORCE, DIAGNOSTIC X-RAY PROTECTION, (Dep't of the Army Technical Bulletin No. TB MED 62/ Dep't of the Air Force Manual No. AFM 161-64, March 23, 1964) [hereinafter referred to as TB MED 62/ AFM 161-64].

the owner of the X-Ray Installation and person in charge thereof.

3.b.2.-3.b.4.

[See HANDBOOK 76, §§ 4.2.b.-4.2.d., at 8.]

Part 4. Radiation Protection Standards — Maximum Permissible Doses

(a) Patients

There is no minimum dose that can be delivered to a patient without an element of risk. All radiation has a factor of risk in it either through possible genetic mutations, malignant changes, or other injuries; however, there is also a definite risk to the patient's well-being or even the patient's life through unrecognized, undiagnosed, or unevaluated disease. Every physician must weigh the risk of the radiation against the value of the X-ray procedure at the time of requesting the examination. It is not a decision to be made by the patient nor should a patient's request for some radiographic procedure be considered as a reason to relieve the doctor of this evaluation. A rule to be followed is that no patient who needs the diagnostic procedure should ever be denied it because of the radiation hazard; but also, there should be no unjustified examination. In cases of early pregnancy, it may be desirable to delay certain examinations where exposure to the fetus may occur if the condition of the patient permits this delay. If an examination is ordered, it is the radiologist's responsibility to see that the amount of radiation delivered to the patient is kept to a minimum through techniques and devices that reduce the dose to the patient.

(b) Radiation Workers

[See HANDBOOK 76, at 22 for Maximum Permissible Doses for radiation workers.]

(c) Non-Radiation Workers

[See HANDBOOK 76, at 22 for Maximum Permissible Doses for non-radiation workers.]

Part 5. Health Provisions

(a) General

[See TB MED 62/AFM 161-64, at 4.]

(b) Personnel Monitoring

[See HANDBOOK 76, § 5.6, at 10.]

(c) Health

[See HANDBOOK 76, § 5.7, at 10.]

Part 6. Design or Modification of X-Ray Installations

(a) Inspector

[See HANDBOOK 76, § 2.1, at 5.]

(b) Design Considerations

[See HANDBOOK 76, § 2.2, at 5-6.]

(c) Design of X-Ray Rooms and Location of Equipment

[See TB MED 62/AFM 161-64, at 5-6.]

Part 7. Structural Detail of Protective Barriers

[See TB MED 62/AFM 161-64, ¶¶ 9.a., 9.h., at 6-7; HANDBOOK 76, § 3, at 6-7.]

Part 8. Conditions Upon Which the Lead Requirement Computations Are Based

[See TB MED 62/AFM 161-64, § 10, at 7.]

Part 9. Specific Requirements for Medical Radiographic Installations

(a) Equipment

9.a.1. The tube housing shall be of the diagnostic type, shockproof, and electrically grounded.

9.a.2. Diaphragms or cones shall be provided for collimating the useful beam and shall provide the same degree of protection as is required of the housing.

9.a.3. The total filtration permanently in the useful beam shall not be less than 2.5 millimeters of aluminum equivalent. This requirement may be assumed to have been met if the half-value-layer is not less than 2.5 millimeters aluminum at normal operating voltages.

9.a.4. An electronic timer shall be provided to terminate the exposure after a preset time or exposure.

9.a.5. A dead-man type of exposure switch shall be provided and so arranged that it cannot be conveniently operated outside a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic tables are excepted from this shielding requirement.

(b) Structural Shielding

9.b.1. All inside walls and doors should have a lead equivalent thickness of one-sixteenth inch (see Part 7 for equivalent thickness of common building material) to a height of seven feet.

9.b.2. The floor should have a lead equivalent thickness of one-sixteenth inch if the area below the radiographic room is or could be occupied.

9.b.3. The ceiling should have a lead equivalent thickness of one/thirty-second inch if the area above the radiographic room is or could be occupied.

9.b.4. If the chest cassette holder is located against the outside wall and the area within 50 feet beyond the outside wall is occupied, the wall behind the chest cassette holder should have a lead equivalent thickness of one-sixteenth inch. This area should extend from the floor to a height of seven feet and extend two feet beyond the sides of the cassette holder.

9.b.5. The X-ray control cabinet should be located in an adjacent room or in a shielded booth within the same room. The control booth should be so arranged that the radiation has to be scattered at least twice before entering the booth. The lead equivalent thickness of the booth wall should be one-sixteenth inch.

9.b.6. An observation window having a lead equivalent thickness of one-sixteenth inch should be provided in the control booth wall for the X-ray technician. The window should provide a convenient, unobstructed view of all areas within the radiographic rooms where a patient may be placed for radiography.

(c) Operating Procedures

9.c.1. No person occupationally exposed to radiation shall be permitted to hold patients during exposure, nor shall any person be regularly used for this service.

9.c.2. Only persons required for the radiographic procedure shall be in the radiographic room during exposure. All such persons, except the patient, should

wear protective aprons and gloves unless measurements indicate that these are not required. No parts of the bodies of these persons shall be in the useful beam.

9.c.3. The exposure of the patient should be kept to the minimum consistent with clinical requirements.

(i) The radiographic field should not be larger than is clinically necessary. Proper collimation can be provided by either an adequate assortment of cones or an adjustable collimator with beam-defining light.

(ii) The gonads of children and persons who have not passed the reproductive age should be protected from the useful beam by the use of careful field collimation or special gonad shields when this will not impair the value of the examination.

Part 10. Specific Requirements for Medical Fluoroscopic Installations

(a) Equipment

10.a.1. The tube housing shall be of the diagnostic type, shockproof, and electrically grounded. (See par. 3.a.6. for recommended method of testing leakage radiation.)

10.a.2 The target-to-panel or target-to-tabletop distance shall not be less than 18 inches.

10.a.3. A cone should extend from the tube housing as near to the panel or tabletop as is practical. Its walls shall provide the same degree of protection as is required of the housing, taking into consideration the incident angle of the useful beam.

10.a.4. The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value-layer is not less than 2.5 millimeters aluminum equivalent at normal operating voltages.

10.a.5. The equipment shall be so constructed that the entire cross section of the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or some sort of image intensification mechanism.

(i) The required lead equivalent of the barrier should be at least 2.0 millimeters and shall not be less than 1.5 millimeters for 100 kvp, should be at least 2.4 millimeters and shall not be less than 1.8 millimeters for 125 kvp, and should be at least 2.7 millimeters and shall not be less than 2.0 millimeters for 150 kvp. This may be constituted by the lead glass of conventional fluoroscopic screens. Special attention must be paid to the shielding of image intensifiers so that neither the useful beam nor scattered radiation from the intensifier itself can produce a radiation hazard to the operator or other personnel.

(ii) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes, this requirement may be assumed to have been met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen, regardless of the position of the screen during use.

(iii) The tube mounting and the barrier (viewing device) should be so linked together that, under conditions of normal use, the barrier (viewing device) always intercepts the useful beam. It is advisable that the exposure automatically terminate when the barrier (viewing device) is moved out of the useful beam.

(iv) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam shall provide a minimum of 2.0 millimeters lead equivalent

protection for 100 kvp, 2.4 millimeters for 125 kvp, and 2.7 millimeters for 150 kvp.

10.a.6. The exposure switch shall be of the dead-man type.

10.a.7. A manually reset, cumulative timing device shall be used which will either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit in one or a series of exposures. The device should have a maximum range of 5 minutes.

10.a.8. For routine fluoroscopy, the exposure rate measured at the panel or tabletop should be as low as possible and shall not exceed 10 roentgen/minutes.

10.a.9. A shield of 0.25 millimeter lead equivalent between the patient and the fluoroscopist is recommended but shall not substitute for the wearing of a protective apron.

10.a.10. A device for covering the Bucky slot during fluoroscopy should be provided. The thickness of material used should provide protection equivalent to at least 0.25 millimeter lead.

10.a.11. Attention should be given to reducing the light intensity in the room.

10.a.12. Mobile fluoroscopic equipment shall meet the requirements of the previous paragraphs of this section except that:

(i) In the absence of a panel or tabletop, a cone or spacer frame shall limit the target-to-skin distance to not less than 18 inches.

(ii) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.

(iii) It shall be impossible to operate the machine when the collimating cone or diaphragm is not in place.

(iv) The maximum permissible dose rate of 10 roentgen/minutes shall be measured at the minimum target-to-skin distance.

(b) Structural Shielding for Fluoroscopes Operating Above 75 kvp or Capable of Spot Film Technique

10.b.1. The lead equivalent thickness of the inside walls should be one/thirty-second inch.

10.b.2. Combined fluoroscopic-radiographic installations are governed by the requirements for radiographic units.

(c) Operating Procedures

10.c.1. Fluoroscopic equipment shall be operated only by properly trained persons authorized by the individual in charge of the installation.

10.c.2. The eyes of the fluoroscopist should be adequately dark-adapted before he uses the fluoroscope. The use of an image intensifier may reduce the degree of adaptation necessary but should not be considered to eliminate the need for it.

10.c.3. The exposure of the patient should be kept to the minimum consistent with clinical requirements.

(i) To this end, the fluoroscopist should take advantage of the dose reducing possibilities presented by high kilovoltage, low milliamperage, field-reducing shutters, and rapid observation.

(ii) When properly used, image intensifiers may significantly reduce both observation time and exposure rate, but they do not inherently accomplish this. Special precautions are necessary when cineradiographic techniques are used, since tube currents and voltages are usually higher than those normally used for fluoroscopy, and exposures to both patients and personnel can become quite large.

(iii) When fluoroscoping persons who have not passed the reproductive age,

special attention should be paid to avoiding exposure of the gonads to the useful beam.

10.c.4. Unless measurements indicate otherwise, protective aprons of at least 0.25 millimeter lead equivalent shall be worn by all persons in the fluoroscopic room, except the patient.

10.c.5. Protective gloves of at least 0.25 millimeter lead equivalent shall be worn by the fluoroscopist during every examination.

10.c.6. The hand of the fluoroscopist shall not be placed in the useful beam unless the beam is attenuated by the patient and a protective glove.

10.c.7. Only persons needed in the fluoroscopic room shall be there during X-ray exposures.

Part 11. Special Requirements for Dental Radiographic Installations

(a) Equipment

11.a.1. The tube housing shall be of the diagnostic type, shockproof, and electrically grounded.

11.a.2. Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing, consideration being given to the obliquity of the rays. The diameter of the useful beam at the cone tip shall be not more than 2.75 inches.

11.a.3. A cone or spacer frame shall provide a target-to-skin distance of not less than 7 inches with apparatus operating above 50 kvp, and 4 inches with apparatus operating at 50 kvp or below.

11.a.4. For equipment operating up to 70 kvp, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 millimeters of aluminum. This requirement may be assumed to have been met if the half-value-layer is not less than 1.5 millimeters aluminum equivalent at normal operating voltages. Equipment operating above 70 kvp shall meet the requirements of 9.a.3.

11.a.5. An electronic timer shall be provided to terminate the exposure after a preset time or exposure.

11.a.6. The exposure control switch shall be of the "dead-man" type.

11.a.7. Where the workload is low enough that shielding is not required for the operator, the installation shall be so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(b) Structural Shielding

11.b.1. The following shielding criteria apply to dental units operating from 60 to 75 kvp. Those dental units operating at higher kilovoltages will require one-sixteenth inch lead equivalent.

11.b.2. All inside walls and doors should have a lead equivalent thickness of at least one-thirty-second inch.

11.b.3. No protective barriers are required on the floor or ceiling.

11.b.4. A protective screen or booth having a lead equivalent thickness of at least one-thirty-second inch should be provided for the X-ray technician and it should be so arranged that the radiation has to be scattered at least twice before entering the protected area.

11.b.5. An observation window having a lead equivalent thickness of at least one-thirty-second inch should be provided in the protective screen or booth. The window should allow a convenient unobstructed view of the patient.

(c) Operating Procedures

11.c.1. In no case shall the film be held by the dentist or his assistant during exposures.

11.c.2. During each exposure, the operator shall stand at least 6 feet from the patient or behind a protective barrier.

11.c.3. Only the patient shall be in the useful beam.

11.c.4. Neither the tube housing nor the pointer cone shall be hand-held during exposures.

11.c.5. Fluoroscopy shall not be used in dental examinations.

11.c.6. The exposure of the patient should be kept to the minimum consistent with clinical requirements.

(i) Fast film shall be used.

(ii) The gonads of children and persons who have not passed the reproductive age shall be protected from the useful beam by the use of collimation or special gonadal shields when this will not impair the value of the examination.

Part 12. Special Requirements for Mobile Diagnostic Equipment

[See HANDBOOK 76, § 8, at 15-16.]

Part 13. Special Requirements for Chest Photofluorographic Installations

[See HANDBOOK 76, § 9, at 16.]