REPORT OF THE
COUNCIL ON HEALTH REGULATORY BOARDS,
DEPARTMENT OF HEALTH REGULATORY BOARDS

The Need for the Regulation of X-Ray Technicians

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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INTRODUCTION

In response to House Joint Resolution 12 (HJR 12) of the 1986 Legislative Session, this report presents to the Virginia General Assembly the findings of a study of the need to regulate x-ray technicians. Specifically, HJR 12 requests the Department of Health Regulatory Boards to:

> study the need to regulate technicians who operate x-ray machines and to review the necessary minimum education, written examinations and continuing education requirements for such technicians who perform their duties under the supervision of an individual licensed by the Board of Medicine, the Board of Dentistry, and the Board of Veterinary Medicine; the feasibility of initiating accreditation based on work experience and of creating three distinct classes of x-ray technicians for dental, medical and veterinary practice.

The study was conducted by a committee of the Council on Health Regulatory Boards (CHRB) which has responsibility to:

> evaluate each health care profession and occupation in the Commonwealth, including those regulated and those not regulated by other provisions of this Title to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed. Whenever the Council determines that the public interest requires that a health care profession or occupation which is not regulated by law should be regulated, the Council shall recommend for approval by the General Assembly next convened a regulatory system necessary to establish the degree of regulation required. (Code of Virginia, §54.955.1)

HJR 12 was passed by the 1986 General Assembly just as the Council was concluding evaluation of a proposal to license radiologic technologists, a special class of x-ray equipment operators. This study, which had been underway for some months, resulted from a proposal by a professional association, the Virginia Society of Radiologic Technologists. This report incorporates the information gathered and conclusions reached as a result of the evaluation of this earlier proposal.

The report consists of the following parts. Part I, Executive Summary, briefly recapitulates the findings and recommendations of the study. Part II sets forth the Legislative, Executive Branch, and CHRB policies, principles, and criteria governing health occupational regulation. Part III describes how the study was conducted and presents the major findings of the study. Part IV concludes the report by summarizing the Council's recommendations on the issues encompassed by the study.

The recommendations of this report were approved unanimously by the Council at its Annual Meeting on October 21, 1986. The text of the report has been approved by the Council's Executive Committee acting in accordance with an express delegation of authority. The Director of the Department of Health Regulatory Boards endorses the findings and recommendations of the Council as presented in this report.

HOUSE JOINT RESOLUTION NO. 12

Requesting the Department of Health Regulatory Boards to study the need to regulate X-ray technicians and to redefine the professional nursing practice.

Agreed to by the House of Delegates, March 7, 1986
Agreed to by the Senate, March 6, 1986

WHEREAS, the delivery of quality health care services is dependent upon the expertise of varied health care professionals, technicians and aides; and

WHEREAS, many physicians, podiatrists, chiropractors, dentists and veterinarians employ technicians or aides to perform tests, including the administration of X-rays; and

WHEREAS, X-rays are a source of ionizing radiation which is potentially dangerous as a possible cause of cancer and genetic damage and can result in death; and

WHEREAS, although X-ray machines are permitted by the Department of Health, the present law and regulations do not require the maintenance and operation of such machines to be monitored, and presently, X-ray technicians or aides are not regulated by the Commonwealth of Virginia; and

WHEREAS, the need to protect the public and workers from unnecessary and dangerous exposure is acute; and

WHEREAS, the profession of nursing is one of the largest groups of health care professionals in the Commonwealth, providing critically needed health services; and

WHEREAS, health care delivery has changed drastically during the past fifteen years, and thirty-four states have updated their nursing practice statutes to accommodate changes in the health care delivery system; and

WHEREAS, the Commonwealth of Virginia has not revised its Nurse Practice Act in fifteen years, and such statutes are in need of review and possible updating; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Health Regulatory Boards is hereby requested to: (i) study the need to regulate technicians who operate X-ray machines and to review the necessary minimum education, written examinations and continuing education requirements for such technicians who perform their duties under the supervision of an individual licensed by the Board of Medicine, the Board of Dentistry and the Board of Veterinary Medicine; the feasibility of initiating accreditation based on work experience and of creating three distinct classes of X-ray technicians for dental, medical and veterinary practice; and (ii) study the need for redefining the professional nursing practice. In studying the issues referred to in (ii) above, the Department shall utilize the resources of the Board of Nursing, the Virginia Nurses Association, the Professional Registered Nurses of Virginia, the Alliance of Nursing Organizations in Virginia, and qualified registered professional nurses.

The Department shall complete its work prior to November 15, 1986, and report its findings soon thereafter.

PART I: EXECUTIVE SUMMARY

The Virginia Council on Health Regulatory Boards (CHRB) has studied whether operators of x-ray equipment in health care settings should be regulated in the Commonwealth. This study expands and includes an on-going study of whether radiologic technologists, a special class of x-ray equipment operators, should be regulated. In addition, the Council addressed other concerns of HJR 12 related to radiation safety: (1) whether there should be specific minimum education, examination, or continuing competency requirements for x-ray technicians who operate under the supervision of physicians, podiatrists, chiropractors, dentists, or veterinarians; (2) whether initiation of accreditation based on work experience is feasible; and (3) whether three distinct classes of x-ray technicians for dental, medical, and veterinary practice should be established and regulated.

The Council study used six formal criteria adopted in 1983 for evaluating whether health professions should be regulated. The most important of these is the determination of whether a risk for harm to the public health, safety, and welfare is created by the unregulated practice of a health occupation.

The study found that there is a risk for harm to the public from overexposure to ionizing radiation and from other problems resulting from faulty x-ray equipment, improper operating procedures, and/or unqualified operators; however, existing Department of Health regulations governing ionizing radiation safety would provide public protection if fully enforced. While these regulations specifically address safety standards for x-ray equipment, procedures, and operators, enforcement has focused almost solely on equipment safety. Licensed practitioners and administrators who are required to register x-ray equipment with the Department of Health are not always aware of their responsibility to ensure that operators under their supervision are "instructed in safe operating procedures and competent in the safe use of equipment" as required by Department of Health regulations.

The Council recommends that the least restrictive form of occupational regulation--a registration program for x-ray equipment operators--be established and operated by the Department of Health. This method of regulation provides public protection while avoiding the costly effects of more restrictive occupational regulatory schemes (certification or licensure). Properly implemented, a registration program can provide public assurance that x-ray equipment operators are competent in the safe use of equipment, as they are now by regulation required to be.

Since radiation safety is equally a concern of the Department of Health and the Department of Health Regulatory Boards, the Council recommends that the Secretary of Human Resources appoint a special joint task force involving representatives from both departments to oversee implementation of the registration program and to study and recommend any appropriate standards that should apply to the registration program. This task force should also study other problems related to safe operation of x-ray equipment and recommend approaches to increased public safety for implementation by the Department of Health and the Department of Health Regulatory Boards. Finally, the Council recommends that the Secretary of Human Resources instruct this task force to prepare a report on its activities and accomplishments for the 1988 Session of the General Assembly.

The costs associated with the operation of the task force can be absorbed from existing revenues of the Department of Health and the Department of Health Regulatory Boards. The costs associated with implementing and operating a registration program for x-ray equipment operators should be offset by registration fees charged for obtaining permits for x-ray equipment operation. Since the Department of Health now maintains a structure for the inspection and permitting of x-ray equipment, the cost of integrating an operator registration program can be held to a minimum.

PART II: POLICIES, PRINCIPLES AND CRITERIA GOVERNING HEALTH OCCUPATIONAL REGULATION

Legislative Policies and Principles

The General Assembly of the Commonwealth of Virginia has enacted the following statement of policy to apply to the regulation of professions and occupations:

> ...the right of every person to engage in any lawful profession, trade or occupation of his choice is clearly protected by both the Constitution of the United States and the Constitution of the Commonwealth of Virginia. The Commonwealth cannot abridge such rights except as a reasonable exercise of its police powers when it is clearly found that such abridgement is necessary for the preservation of the health, safety and welfare of the public.
>
> (Code of Virginia §54-1.17)

There are five state regulatory methods for insuring public protection in Virginia. The first two methods do not apply directly to occupational regulation, but may be selected in lieu of the registration, certification, or licensure of individuals.

Private civil actions and criminal prosecutions: Whenever the state finds that existing laws are not sufficient to protect the public, it may provide by statute for more stringent grounds for civil action and criminal prosecution.

Inspection: The activities and premises of persons in certain occupations are subject to periodic inspections to ensure that the public's health, safety, and welfare are protected. Anyone is allowed to practice the occupation without meeting specific entry criteria. However, an injunction can be issued to prevent persons who do not meet the inspection standards from engaging in the occupation.

Registration: Under this type of regulation, any person may engage in an occupation, but he or she is required to submit information concerning the location, nature, and operation of the practice.

Certification: As a form of regulation, certification recognizes persons who have met certain educational and experience standards to engage in an occupation. Although any one may practice the occupation, only those who are certified may use the occupational title.

Licensure: Under this method of regulation, it is illegal for anyone to engage in an occupation without a license, and only persons who possess certain qualifications are licensed.

In addition, in §54-1.26.B, a number of general factors are designated for use in assessing the proper degree of regulation, if any, that should be established for occupations and professions. While these are general, the Council on Health Regulatory Boards has determined that they should apply to health professions and occupations and has published them in its procedural handbook adopted for use by organizations or others requesting evaluation of proposals for health occupational regulation. These factors are:

> Whether the practitioner performs a service for individuals involving a hazard to the public health, safety, or welfare, if unregulated.
>
> The view of a substantial portion of the people who do not practice the particular profession, trade, or occupation.
>
> The number of states which have regulatory provisions similar to those proposed.
>
> Whether there is sufficient demand for the service for which there is no substitute not likewise regulated and this service is required by a substantial portion of the population.
>
> Whether the profession, trade, or occupation requires high standards of public responsibility, character, and performance of each individual engaged in the profession, trade, or occupation, as evidenced by established and published code of ethics.
>
> Whether the profession, trade, or occupation requires such skill that the public generally is not qualified to select a competent practitioner without some assurance that he or she has the minimum qualifications.
>
> Whether the professional, trade, or occupational associations do not adequately protect the public from incompetent, unscrupulous, or irresponsible members of the profession, trade, or occupation.
>
> Whether current laws which pertain to public health, safety, and welfare generally are ineffective or inadequate.
>
> Whether the characteristics of the profession, trade, or occupation make it impractical or impossible to prohibit those practices of the profession, trade, or occupation which are detrimental to the public health, safety, and welfare.
>
> Whether the practitioner performs a service for others which may have a detrimental effect on third parties relying on the expert knowledge of the practitioner.

The Council has employed these legislative principles and policies in evaluating the need to regulate operators of x-ray equipment in the health field.

Executive Branch Policy and Council Criteria

In evaluating proposals for health professional or occupational regulation, CHRB is also guided by the following regulatory policy expressed by Governor Gerald L. Baliles in Executive Order Five (86):

> While recognizing that the state government has an affirmative and inescapable duty to enforce regulations that protect the public safety and welfare, it is the policy of the Commonwealth of Virginia to conduct required regulatory activities in a manner that intrudes to the least possible extent into the legitimate functions of private enterprise and individual citizens. It is also the policy of the Commonwealth to strive to draft, adopt and enforce regulations that do not unnecessarily burden the activities of private businesses and citizens.

Finally, since 1983, the Council has evaluated regulatory proposals using six formal criteria adopted by CHRB following an extensive study of the regulation of health occupations and professions in Virginia and in other states. These criteria are:

CRITERION 1*: The unregulated practice of an occupation will harm or endanger the health, safety and welfare of the public. The potential for harm is recognizable and not remote or dependent on tenuous argument.

CRITERION 2: The practice of an occupation requires a high degree of skill, knowledge and training, and the public requires assurances of initial and continuing occupational competence.

CRITERION 3: The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.

CRITERION 4: The scope of practice of an occupation is distinguishable from other licensed and unlicensed occupations.

CRITERION 5: The economic impact on the public of regulating this occupational group is justified.

CRITERION 6: There are no adequate alternatives to regulation (i.e., licensure, statutory certification, or registration) that will protect the public.

*A prerequisite for a health occupational group to be regulated.

PART III: STUDY OF THE NEED TO REGULATE X-RAY TECHNICIANS

Background to the Issue

Radiologic health services began with the diagnostic use and application of x-rays and other forms of ionizing radiation for only a limited number of health-related purposes. With medical and technological advances, new equipment, procedures, and categories of operators were created. The 1980 Decennial Census reported that 111,700 individuals in the United States indicated their employment as "radiology services personnel." The Virginia Employment Commission estimated that there were 1,190 individuals employed as "x-ray technicians" and 680 as "radiologic/nuclear medicine technicians" in the Commonwealth in 1980. Under the general title of radiologic technologist, the Council on State Governments in a 1984 report distinguished four occupational titles of practitioners (radiographers, radiation therapy technologists, nuclear medicine technologists, and dental assistants who make radiographs) regulated by one or more states. A list of occupational titles and state regulatory mechanisms affecting these titles is provided in Appendix 1.

House Joint Resolution 12 was introduced at an important point in the Council's ongoing study of a proposal for licensure of radiologic technologists. Using the formal criteria for evaluating proposals for regulation, the Council found from evidence presented at a public hearing and from other investigations that some risk for harm to the public exists as a result of faulty equipment, improper operating procedures, and/or unqualified operators. The evidence also suggested that the need to regulate the full range of professions and occupations using x-ray equipment should be considered concurrently with evaluation of the need to license radiologic technologists.

The Council determined that although a need for public protection exists, licensure of radiologic technologists would be overly restrictive as a strategy for managing demonstrable risk. Abstracts of articles on risk of harm and on occupational regulation as a risk management strategy in the professional and scientific literature and in the public media appear in Appendix 2.

In responding to the proposal to license radiologic technologists, the Council was aware of the need to review the range of health care settings in which x-ray equipment is used as well as the categories of personnel who operate this equipment. The Council's study of these issues was enhanced by the interest and participation of the Radiation Advisory Board (RAB). Established within the Department of Health (DOH), the RAB's membership consists of representatives from industry, labor, agriculture, and several scientific and health professions.

The statutory authority of RAB includes the review and evaluation of Virginia's policies and programs relating to ionizing radiation and formulation of recommendations to the Commissioner and Board of Health on matters relating to regulation of sources of ionizing radiation. The RAB's delegation, however, "shall not be construed to limit the kind or amount of

radiation that may be intentionally applied to a person for diagnostic or therapeutic purposes by or under the direction of a licensed practitioner of the healing arts nor the qualifications of such a practitioner to use in his practice radiation produced by an x-ray machine or device not subject to federal regulation heretofore. Such a practitioner may, however, be subject to any registration requirements established by the Board [of Health]."

While it is clear that statutory provisions differentiate between regulatory standards for x-ray equipment--typically the concern of the Board and Department of Health and the Radiation Advisory Board--and standards for credentialing health personnel who operate this equipment--typically a function of the Department of Health Regulatory Boards--in reality, these distinctions become blurred.

In its early deliberations, the Council on Health Regulatory Boards found that the regulations of the Department of Health (Ionizing Radiation Rules and Regulations, 1980) establish standards for both x-ray equipment safety and for the safe operation of this equipment. In light of these interdepartmental implications, the Council decided that it was necessary to expand the scope of its study to examine the possible coordination of any potential program for personnel credentialing with the existing program by which the Department of Health regulates the safety of x-ray equipment, including the operation and maintenance of this equipment.

The Council's anticipation of a broader study was reaffirmed by HJR 12. The Resolution notes that "physicians, podiatrists, chiropractors, dentists, and veterinarians" employ technicians and aides "to perform tests and other procedures requiring the use of x-ray equipment." HJR 12 continues by observing that present DOH regulations "do not require the maintenance and operation" of x-ray machines to be monitored and that, at present, x-ray technicians are "not regulated." While these observations are technically correct, the Council found in its expanded study that regulations of the Department of Health do contain substantial provisions for the maintenance and safe operation of x-ray equipment. (Excerpts of relevant sections of DOH regulations appear in Appendix 3.)

In the view of the Council, the public interest is typically better served through the enforcement and strengthening of existing regulatory programs than by the creation of costly parallel or redundant new programs of state regulation.

Process of the Study

To supplement its earlier evaluation which included an informational hearing on the proposal to license radiologic technologists held in September 1985, the Council's expanded study consisted of the following activities:

- HJR 12 cites physicians, podiatrists, chiropractors, dentists and veterinarians as health care professionals who administer x-rays or employ technicians or aides to do so. In March 1986, a meeting was convened which included representation by members of the Board of Medicine (which licenses physicians, podiatrists, and chiropractors), the Board of Dentistry, the Board

of Nursing, and the Board of Veterinary Medicine. This meeting explored the regulatory mechanisms, if any, that were in place and used by these boards to ensure safe operation of x-ray equipment in health settings. The Council determined that it would be helpful to include the Board of Nursing in this exploratory meeting with representatives of Boards directly involved with regulation of the health professions named in HJR 12.

- On June 12, 1986, a widely advertised and well-attended informational hearing was held in Richmond inviting comment from all relevant publics on the particulars of HJR 12.

- An extensive review of the policy literature on radiation safety was conducted. This review included special attention to relevant federal studies and policies and to the regulatory mechanisms used or under consideration by other states to credential x-ray equipment operators in health care settings.

- A meeting of Council members and staff with DOH officials was held on September 2, 1986, to discuss DOH and DHRB programs and the need for coordination of activities related to x-ray safety.

Findings of the Study.

As a result of these study activities, the following findings and observations are submitted.

1. Although some inconsistencies of approach exist among the health regulatory boards regarding the regulation of x-ray machine operators, there is no evidence that these inconsistent approaches create a risk of harm to the public.

An initial review of complaints and disciplinary actions of boards within the Department Health Regulatory Boards (DHRB) and of the claims experience of the Virginia Insurance Reciprocal, Inc., was conducted. No complaints involving the improper operation of x-ray equipment were identified by DHRB boards. The Virginia Insurance Reciprocal, Inc., which insures more than 80 hospitals and 3,000 physicians in Virginia, reported only one claim involving alleged negligent acts by medical radiation workers during the past eight years. These findings indicate that the risk of harm to the public from x-ray exposure is being successfully managed in most settings.

A review of existing and proposed approaches of DHRB boards to risk management was also conducted. Table 1 presents current and proposed approaches to the regulation of x-ray operators of the boards of Dentistry, Medicine, Nursing and Veterinary Medicine.

Table 1:
CURRENT AND PROPOSED BOARD APPROACHES TO
THE REGULATION OF X-RAY EQUIPMENT OPERATORS

	Current	Proposed or Recommended
Dentistry	Satisfactory completion (by a person not otherwise licensed by the Board of Dentistry) of a Board-administered examination; or satisfactory completion of a course and/or examination in radiation safety from an approved institution or organization.	Proposes regulations eliminating Board examination in favor of satisfactory completion of a clinical and/or laboratory and didactic course and examination from an approved institution or program.
Medicine	No regulations; licensed physicians accept responsibility for x-ray technicians or aides under their supervision.	Recommends some form of regulation regarding safety, which may be personnel credentialing other than licensure.
Nursing	No regulations; nurses receive no basic generic courses in the operation of x-ray equipment, nor is this an expectation or requirement of nursing practice.	No proposals or recommendation.
Veterinary Medicine	Extensive minimum requirements for facilities, equipment, and safe operation of x-ray equipment. Extensive educational and testing requirements, including clinical training.	Proposes including the use by a DVM of an unqualified operator to operate x-ray equipment as unprofessional conduct.

The current approaches are paraphrased from existing regulations of these boards. These regulations were subjected to a comprehensive review in 1984-85 under the terms of the regulatory reform measures mandated by former Governor Charles S. Robb. All relevant publics were invited to comment on these regulations. As a result of public comments, changes in the regulations of the boards of Dentistry and Veterinary Medicine affecting the operation of x-ray equipment have been proposed.

There were no public comments relative to the boards of Nursing or Medicine, possibly because no requirements affecting the operators of x-ray equipment are in place in the regulations of these boards. In the case of Nursing, members of the Board assert that although nurses may be found to operate x-ray equipment, nurses do not perform such acts as a part of the practice of nursing. In the case of Medicine, Board members are aware of

the lack of regulatory provisions. Although acknowledging a possible need for credentialing, members of the Board of Medicine oppose licensure as an overly restrictive quality-control mechanism. If a less restrictive regulatory mechanism (certification, registration) were to be adopted, these Board of Medicine members recommend that the same agency administer both equipment safety regulations and those affecting x-ray equipment operators.

2. Harm to the public from ionizing radiation comes from overexposure to X-rays, involving either separately or through interaction, poorly maintained equipment, poor standards or procedures in operating equipment, or poor technique in achieving appropriate diagnostic image quality of radiographs. The Council believes that the DOH standards governing equipment and the operation of equipment are adequate but these standards are neither well enforced nor adequately understood by health professionals.

Under the terms of the DOH Ionizing Radiation Rules and Regulations (1980) "any person who possesses or administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system is required...to register this equipment [§.2(bs)]."

The registrant is further required to ensure that registered equipment is periodically inspected by "qualified experts" and that individuals operating the x-ray system are "adequately instructed in safe operating procedures and competent in the safe use of the equipment." Further requirements stipulate that written safety rules be provided each equipment operator and that the operator demonstrate familiarity with these rules. Specific operating procedures, such as the required use of protective shielding for patients and workers appear throughout those sections of regulations specific to health care settings.

DOH regulations applicable to equipment are extensive and, while it is not appropriate for the Council on Health Regulatory Boards to assess the adequacy of these requirements, a number of problems were identified by individuals and organizations commenting on Department of Health programs during the Council's review.

- DOH procedures and practices do not result in universal registration of x-ray equipment.

- Health practitioners do not always understand DOH requirements that equipment be registered and operators fully instructed in safe use of the equipment.

- The system for use of "qualified experts" who act as the Department's primary mechanism for monitoring x-ray equipment is imperfectly understood and may require review. The roles and functions of these experts, the standards and procedures for their qualification, and their responsibilities as well as those of equipment manufacturers, "assemblers", and "registrants" need to be clearly delineated and widely disseminated to all affected parties.

° DOH issues no publicly visible evidence (decal, registration permit or certificate, etc.) of compliance with equipment safety standards or standards of safe operation.

° DOH procedures for independent surveys of x-ray equipment conducted by DOH staff investigators, and for follow-up of serious problems identified by "qualified experts" should be strengthened.

Some of these problems are acknowledged by DOH in a statement by the Bureau of Radiological Health, which is reprinted in Appendix 4.

The concern for technique in the operation of x-ray equipment arises from the possibility of poor quality radiographs that may result in misdiagnosis or the need to repeat x-ray procedures. Again, DOH regulations specify that the registrant is responsible for insuring procedures for minimizing patient and personnel exposure, i.e., that exposure is the minimum required for "images of good diagnostic quality." Licensed health practitioners (physicians, dentists, veterinarians, etc.) are responsible for the appropriate diagnosis of health conditions, and regulation of their licensed practice is assured by existing statutory and regulatory standards of care.

3. The setting in which x-ray equipment is used varies, and the degree of risk of harm to the public appears to vary depending on the setting involved. There was less concern expressed during the Council's study for x-ray safety in hospitals and large clinics than for equipment and procedures used in independent small practices or in isolated rural settings. From the evidence at hand, it is more likely that hospitals and large clinics are in compliance because they are more likely to be surveyed. Survey and safety requirements are universal, however, and should be enforced without regard to convenience or other factors.

The language of HJR 12 specifically requests study of the need to regulate technicians who operate x-ray machines and review of the necessary minimum education, examinations, and continuing education requirements for technicians who work under the supervision of professionals licensed by the boards of Dentistry, Medicine, and Veterinary Medicine as well as study of the feasibility of "accreditation based on work experience and of creating three distinct classes of x-ray technicians for dental, medical, and veterinary practice."

Responding to these specifics, the Council found little guidance in its review of the literature and of federal or state policies affecting the credentialing of operators of x-ray equipment or the accreditation of formal or informal training or work experience.

The Council of State Governments (CSG) reported in 1986 that 16 states license radiologic technologists/technicians and two states license nuclear medicine technologists. A more complete tabulation of occupational titles and levels and methods of regulation was published by CSG in 1984 (see Appendix 1). This earlier report also included a survey of the creden-

tialing of dental assistants who make radiographs. The 1984 report documents a variety of methods of credentialing and other requirements, ranging from a requirement for training, with no resulting credentialing, through each of the standard levels of occupational regulation--registration, certification, licensure--with no discernible relationship between requirements and credentials awarded.

Within the federal establishment, the U.S. Department of Health and Human Services (HHS) has issued standards for the accreditation of educational program for persons who perform radiologic procedures and for their certification as directed by the Consumer-Patient Radiation Health and Safety Act of 1981. The Act also directed HHS to prepare and transmit a Model Statute for the regulation of radiologic personnel by the states. In transmitting the Model Statute, HHS emphasized that enactment by any state is totally discretionary and that persuasive evidence has not been found to show that licensing or other credentialing is "likely to affect patient safety in any measurable way, even in the long run."

The Department of Health and Human Services, therefore, did not strongly recommend its Model Statute, but emphasized instead the value of an active program of regulation of radiologic equipment, that also devoted substantial effort to assuring safety in operation of the equipment. HHS recommended a program of short-term training for personnel, combined with safety design features, that would minimize the need for extensive training.

These observations point to a finding of the Council. While there is justifiable concern for public risk, and states and the federal government are grappling with mechanisms to manage this risk, highly restrictive credentialing schemes such as licensure do not confront directly the dominant risk the public face--overexposure. It is virtually impossible to isolate the separate contributions to overexposure made by equipment and procedures on the one hand, and the characteristics of operators on the other. One scientific study of the effects of licensure of operators on overexposure estimates, however, that universal requirements for licensure would reduce the population x-ray dose by a maximum of one or two percent (Audet and Johnson, 1985; see Appendix 2).

4. In summary, the Council finds that risk of overexposure exists in three areas--from x-ray equipment, the operation of x-ray equipment, and technique used in radiologic procedures. The public can be protected from this risk by enforcement of existing regulatory requirements for equipment and its operation. A need does exist, however, for enforcement of the general requirement of the Department of Health that operators of x-ray equipment be "adequately, instructed in safe operating procedures and competent in the safe use of the equipment." The mechanism proposed to promote enforcement of this provision is the registration of operators, monitored and enforced through the operation of the DOH equipment inspection program.

This finding leaves unanswered for the present whether minimum standards of operator knowledge and competence may be established that provide additional protection at a cost commensurate with benefit. The Council believes that the proper examination of this question will require more time and that recommendations on specific operator standards and education and training should be delayed until further study is accomplished. Furthermore, proper resolution of these questions will require study by experts in radiation safety and in the professions of medicine, dentistry and veterinary medicine. In the section that follows, the Council's recommendations are presented for the establishment of a task force to conduct this study and to coordinate the implementation of other recommendations made in this report.

PART IV: RECOMMENDATIONS

The Council on Health Regulatory Boards makes the following recommendations based on its study of the need to regulate operators of x-ray equipment in the health field.

1. A registry of all operators of x-ray equipment in the health field should be established and integrated into the existing regulatory program of the Department of Health. The Secretary of Human Resources should be directed by the General Assembly to appoint a special task force to develop a plan for the orderly implementation of the registration program.

2. In addition, the task force should be instructed to evaluate whether specific education and/or training requirements prerequisite to registration are appropriate and to determine whether these standards ought to be universal or specific to practice settings (i.e., dentistry, medicine, podiatry, chiropractic, veterinary medicine).

3. The task force to be appointed by the Secretary of Human Resources should consist of the following:

   a. Three representatives of the Department of Health (including the Board of Health and the Radiation Advisory Board) to be nominated by the Commissioner of Health.

   b. One representative each of the boards of Dentistry, Medicine and Veterinary Medicine to be nominated by each board.

   c. Two citizen members--one of whom shall be a member of the Council on Health Regulatory Boards and the other a citizen member of the Board of Dentistry, the Board of Medicine, or the Board of Veterinary Medicine--to be nominated by the Council on Health Regulatory Boards.

4. Staffing for the task force should be provided jointly by the Department of Health and the Department of Health Regulatory Boards.

5. Expenses for the operation of the task force should be provided jointly by the Departments of Health and the Department of Health Regulatory Board and established by a letter of agreement between the two departments.

6. Expenses for the operation of the registration program should be met by registration fees which should be paid either by equipment registrants or registered operators. It is recognized that the Department of Health will require additional initial resources for establishing and operating the registration program. The task force should identify the resources initially and continually required and recommend a plan for funding initial and continuing expenses primarily or exclusively from registration fees.

7. In addition to the specific charges to the task force identified above, the task force should:

   a. Insure public review of the regulations of the Department of Health and of the Boards of Dentistry, Medicine and Veterinary Medicine, and prepare recommendations for revisions or additions to these regulations based on this review. Specific recommendations should be prepared to insure compliance with all appropriate regulations.

   b. Insure that the regulated entities of all appropriate health regulatory boards and of the Department of Health are notified fully of their responsibilities as registrants of x-ray equipment under the provisions of Ionizing Radiation Rules and Regulations 1980.

   c. Recommended additional mechanisms for improving the coordination of the regulatory programs affecting x-ray equipment operation conducted by the DOH and DHRB.

8. The Secretary of Human Resources should establish a timetable for the accomplishment of the specific tasks assigned to the Task Force. This timetable should include preparation of a report on progress to the 1988 Legislative Session of the General Assembly.

APPENDIX 1

STATE LICENSURE REQUIREMENTS FOR RADIOGRAPHERS, RADIATION THERAPY TECHNOLOGISTS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIOLOGIC PORTIONS OF DENTAL ASSISTANTS' SERVICES

RADIOGRAPHERS

STATE	Accepts CAHEA/JRC Accredited Programs	Exam Given	Certificate Accepted
Arizona	Yes	ARRT, State[4], MRTBE	ARCRT, ARRT
California	No[1]	State	ARRT[2]
Florida	Yes	State[4], ARRT[3], ARCRT	ARRT, ARCRT
Hawaii	Yes	State[6]	None
Illinois	Yes	State, NMTCB	ARRT
Indiana	Yes	ARRT, State[4]	ARRT
Iowa	Yes	None	ARRT
Kentucky	Yes, with jnt. site visit	ARRT, State[4]	ARRT
Maine	Yes	State, ARRT	ARRT
Montana	Yes	ARRT, State[5]	ARRT
New Jersey	Yes, with jnt. site visit	ARRT, State[5]	ARRT
New York	Yes, with jnt. site visit	ARRT	ARRT
Oregon	Yes	ARRT, State[4]	ARRT,ARCRT
Vermont	Yes	ARRT, State[4]	ARRT[2]
West Virginia	Yes, with jnt. site visit	ARRT	ARRT
Puerto Rico	No	State & 1 yr. service	

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1 CAHEA accreditation is considered when approving programs

2 With conditions

3 ARRT exam given to candidates for "advanced" certification.

4 For limited license only

5 Permits are gien in lieu of license for hardship areas

KEY:

ARRT - American Registry of Radiologic Technologist

ARCRT - American Registry of Clinical Radiography Technologists

CAHEA/JRC - Committee on Allied Health Education and Accreditation/Joint Review Committee on Education in Radiologic Technology

State Training, Examinations and Credentialing for Dental Assistants Making Radiographs, 1984

State	Required training	Exam Required		Credential Issued
		Written	Clinical	
Arizona	Approved Course	Yes	Yes	Certificate
California	None	Yes	No	Certificate
Colorado	Approved Course	No	No	None
Florida	Approved Course[2]	No	No	Certificate
Illinois	Approved Course	No	No	None
Indiana	Approved Course	Yes	No	Certificate
Iowa	Approved Course	Yes	No[3]	Certificate
Kentucky	Approved Course	Yes	No	Certificate
Maine	None	Yes	No	Registration
Maryland	Approved Course	Yes	No	Certificate
Michigan	Approved Course	Yes	Yes	None
Minnesota	Approved Course	Yes	No	Registration
Mississippi	Home Approved Course[2]	Yes	No	Permit
Montana	None	Yes	Yes	Certificate
Nebraska	Approved Course	No	No	None
New Hampshire	Approved Course	Yes	Yes	Formal List
New Jersey	Approved Course	Yes	No	License
New Mexico	Approved Course	Yes	No	Registration
N. Carolina	Approved Course	No	No	None
N. Dakota	Approved Course	No	No	Certificate
Oklahoma	Approved Course	Yes	No	Certificate
Oregon	Approved Course	Yes	Yes	Certificate
Rhode Island	Approved Course	No	No	Formal Letter
South Dakota	Approved Course	Yes	Yes	Registration
Tennessee	Approved Course	Yes	No	Registration
Vermont	Approved Course	No	No	Registration[4]
Virginia	Approved Course	Yes	No	Certificate

[2]Also requires 6 months on-the-job training before certificate is awarded.
[3]Employing dentist must attest to clinical competency of assistant after observing the dental assistant for a minimum period of 30 days.
[4]Sticker that says "Privileges in Dental Radiology" is placed on the licensee's registration card.

STATE LICENSURE FOR RADIATION THERAPY TECHNOLOGISTS

STATE	Accepts CAHEA/JRC Accredited Programs	Exam Given	Certificate Accepted
ARIZONA	Yes	ARRT STATE State under contract with MRTBE	ARRT
CALIFORNIA	Yes	STATE ARRT	ARRT[1]
FLORIDA	Yes	State[2] ARRT ARCRT	 ARRT ARCRT
HAWAII	Yes	State	None
ILLINOIS	Yes	State under contract with ARRT	ARRT
MAINE	Yes	ARRT	ARRT
NEW JERSEY	Yes, with joint site visit	ARRT State under contract with ARRT	ARRT[1]
NEW YORK	Yes, with joint site visit	ARRT	ARRT Accept license other states
OREGON	Yes	ARRT	ARRT
VERMONT	Yes	ARRT	ARRT
PUERTO RICO	No	State and 1 year Service	None

1 With conditions
2 State developed exam is for technologists without formal training

STATE LICENSURE REQUIREMENTS FOR NUCLEAR MEDICINE TECHNOLOGISTS

STATE	Accepts CAHEA/JRC Accredited Programs	Exam Given	Certificate Accepted
ILLINOIS	Yes	State under Contract with NMTCB	ARRT, NMTCB ASCP
MAINE	Yes	State under Contract with NMTCB	NMTCB, ASCP
NEW JERSEY	Yes, with joint site visit	State under Contract with NMTCB	ARRT, NMTCB ASCP
VERMONT	Yes	ARRT	ARRT, NMTCB
PUERTO RICO	No	State and 1 year Service	None

1 NMTCB certificate holders must be graduates of approved schools; on-the-job training is not recognized

APPENDIX 2

ANNOTATED REFERENCES TO SOME STUDIES AND ARTICLES REGARDING RISK OF X-RAY EXPOSURE AND EFFECTS OF CREDENTIALING

Faulty X-ray Devices, Untrained Operators Overdose US Patients," The Wall Street Journal, December 11, 1985.

1. Experts disagree about whether diagnostic levels of radiation are harmful.

2. Food and Drug Administration studies show the amount of radiation from chest x-rays varies more than one hundredfold depending on where one gets it; 20 percent of the country's 165,000 x-ray operators don't have any formal training.

3. Officials in various states estimate that from 15 percent to 50 percent of machines inspected don't meet state patient-safety standards. Only 17 states have training requirements for x-ray machine operators.

4. Machine function, operating procedures, and practitioner techniques interact in creating risk, in the limiting of x-ray beams to the affected body area (collimation), and proper positioning of the body, the developing of film, and the proper use of screens and shielding. Credentialing mechanisms appropriately look at the complex ways by which risk is created.

5. Some experts place most blame on lack of awareness of safety procedures and ignorance of requirements maintained by inspection programs.

6. Understaffed and burdened with other responsibilities, many state inspection programs focus on high-use facilities, thereby inadequately handling offices of nonradiologist practitioners or falling behind in inspection schedules.

"Nursing Home X-rays Called Costly, Dangerous," The Washington Post, October 10, 1986.

1. US Department of Health and Human Services reports that state requirements that nursing home residents receive chest x-rays are obsolete, costly, and dangerous.

2. Skin testing should take the place of routine x-rays in testing for tuberculosis. Virginia does not require x-rays; however, inspectors found records on 524 x-rays in 16 nursing homes, 40 percent of which were given only because of admissions policies. These cost Medicare more than $373,000 a year in Virginia.

3. Joint Commission on Accreditation of Hospitals rejected routine x-rays for admissions in 1979.

"The Influence of Diagnostic Radiography on the Incidence of Breast Cancer and Leukemia," John S. Evans, ScD, et al., The New England Journal of Medicine, September 25, 1986.

1. Diagnostic x-rays are the dominant manmade source of radiation, accounting for 40 percent of total exposure. Radiation in large enough dosages is a proved carcinogen, and no level of exposure appears to be entirely without some risk. Data were analyzed on types and numbers of radiographic examinations performed during one year in a group of about 75,000 patients in Maine. Age-specific annual dosages were calculated, as were expected numbers of cases of cancer of the bone marrow and breast, which are among the most frequent radiation-induced cancers. The types of films that contribute to the dose to to these areas represent most of the workload of radiology departments.

2. Results of the study regarding radiation-induced carcinogenesis indicate that the likely number of new cases of leukemia is about 250 cases per year, or about one percent of all cases. The likely number of new cases of induced breast cancer is about 800 per year, or about .7 percent of all cases. Although these are small fractions of total cases, lifetime risks to the person who is average in terms of susceptibility to these cancers and exposure to radiation are not small enough to be ignored.

3. The benefits of diagnostic radiography greatly outweigh the hazards; however, care must be made to minimize dosages. Avoiding prescribing clinically unproductive examinations, suitable training in radiology for physicians, using the smallest number of films and shortest exposure times, proper shielding, and careful machine operation are all parts of this vigilance.

"Credentialing of Diagnostic X-ray Technologists: A Question of Public Health Impact," Michael Audet and David Johnson, American Journal of Public Health, March 1985, V75/N3.

1. The question investigated is "to what extent do credentials of operators affect the amount of unnecessary radiation exposure to the public."

2. The study presents estimates of the number of diagnostic x-ray examinations performed in the US, the population dose delivered, the percentage of that dose contributed by credentialed and noncredentialed operators, and one measure of performance (collimation of the x-ray beam).

3. Data resulting from these estimates indicate better collimation for chest examinations by credentialed operators in the same type of facility; however, the data indicate these differences may be more related to the specific facility than to credentialing. If these differences are related to credentialing, the data suggest credentialed operators could reduce the radiation dose by about 15 percent.

4. For other x-ray examinations investigated, the potential reduction in dose from the improved collimation by credentialed operators is less than one percent.

5. Although limitations on the available data recommend caution, the study concludes that even if all noncredentialed operators of x-ray equipment were eventually required to obtain some type of credential or to meet some criteria for competence, the impact on population dose would be small.

6. Minimum standards of knowledge and competence may have a positive effect on protection practices; however, there is little evidence in the study that more extensive education and credentialing requirements will result in improved patient protection in the operators' performance.

APPENDIX 3

SELECTION FROM IONIZING RADIATION RULES AND REGULATIONS (1980)

DEPARTMENT OF HEALTH

PART F
X-RAYS IN THE HEALING ARTS

Sec. F.1 Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this part are in addition to, and not in substitution for other applicable provisions of these regualtions.

Sec. F.2 Definitions. As used in this part, the following definitions apply:

(a) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(b) "Added filtration" means any filtration which is in addition to the inherent filtration.

(c) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy 1/ affording the same attenuation, under specified conditions, as the material in question.

(d) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem.

(e) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy 1/ or other materials having equivalent attenuation.

(f) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

(g) "Barrier" (See "Protective Barrier").

(h) "Beam axis" means a line from the source through the centers of the x-ray fields.

(i) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(j) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

1/ The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

(ah) "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

(ai) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

(ai-2) "High Level Control" means a control which can be activated by the fluoroscopic x-ray operator when an exposure rate of more than 5 R/min. is desired when viewing a structure of high density. When using high level control, the maximum exposure rate shall be 15 R/min.

(aj) "HVL" (See "Half-value Layer").

(ak) "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

(al) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(am) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

(an) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(ao) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(ap) "Irradiation" means the exposure of matter to ionizing radiation.

(aq) "Kilovolts peak" (See "Peak tube potential").

(ar) "kV" mean kilovolts.

(as) "kVp" (See "Peak tube potential").

(at) "kWs" means kilowatt second. It is equivalent to E-03 kV.mA.s, i.e,

$$(A)\text{kWs} = (X)\text{kV} \times (Y)\text{mA} \times (Z)\text{s} \quad \frac{\text{x kWs}}{\text{E-03kV x mA x s}} = \frac{\text{XYZ kWs}}{\text{E-03}}$$

(au) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(bd) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(be) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

(bf) "PID" (See "Position indicating device").

(bg) "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite sourcesurface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

(bh) "Primary protective barrier" (See "Protective Barrier").

(bi) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

(bj) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

(2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(bk) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.

(bl) "Qualified Expert" means an individual who has demonstrated by training and experience to the satisfaction of the registrant or licensee that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. Criteria for designation as a Qualified Expert are set forth in Appendix D. Pursuant to Appendix D, the Commissioner may disqualify an individual from the designation of Qualified Expert for just cause as described therein.

(bm) "Radiation detector" means a device which in the presence of radiation provides by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(bn) "Radiation therapy simulation system" means a fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(bo) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

(bp) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(bq) "Rating" means the operating limits as specified by the component manufacturer.

(br) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

(bs) "Registrant", as used in this part, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by Parts A and B of these regulations to register with the Commissioner.

(bt) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(bu) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

(bv) "Secondary protective barrier" (See "Protective barrier").

(bw) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(bx) "SID" (See "Source-image receptor distance").

(by) "Source" means the focal spot of the x-ray tube.

(bz) "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

(ca) "Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

(cb) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(co) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

(cp) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

(cq) "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

(cr) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(cs) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

(ct) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(cu) "X-ray subsystem" means any combination of two or more components of an x-ray system.

(cv) "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

Sec. F.3 General Requirements

(a) Administrative Controls.

(1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system which have been registered with the Commissioner. The registrant or the registrant's agent shall assure that the requirements of F.3(a)(1) are met in the operation of the x-ray system(s).

(i) An x-ray system which does not meet the provision of these regulations shall not be operated for diagnostic or therapeutic purposes if so directed by the Commissioner.

(ii) Individuals who will be operating the x-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment.

(iii) Section deleted.

(iv) Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.

(v) Except for patients who cannot be moved out of the room, only the staff and necessary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shll be positioned such that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent.

(b) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(vi) Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(vii) Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(a) exposure of an individual for training, demonstration or other non-healing-arts purposes; and

(b) exposure of an individual for the purpose of healing arts screening except as authorized by F.3(a)(1)(xi).

(viii) When a patient or film must be provided with auxiliary support during a radiation exposure:

(a) mechanical holding devices shall be used when the technique permits. The safety rules, required by F.3, shall list individual projections where holding devices cannot be utilized;

(b) written safety procedures, as requied by F.3(a)(1)(iv), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(c) the human holder shall be protected as required by paragraph F.3(a)(1)(v);

(d) individuals shall be used to hold film or patient only when necessary, and no individual shall be used routinely for this purpose to the exclusion of others who might share the task.

(e) Section deleted.

(f) Section deleted.

(g) Section deleted.

(ix) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include, but not limited to:

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary radiographic installation.

(d) X-ray systems subject to F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

(x) All individuals who are associated with the operation of an x-ray system are subject to the requirements of D.101 and D.102 of these regulations. In addition:

(a) When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(1) When an apron is worn and only one monitoring device is in use, the device shall be worn at the collar outside the apron.

(2) The dose to the whole body or the maximum dose attributed to the most critical organ shall be recorded in the reports required by D.401 of these regulations. If more than one device is used each dose shall be recorded and identified with the area where the device was worn on the body.

(3) The position on the body at which a particular monitoring device is worn and used shall not be changed during any calendar quarter.

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(ix) Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Commissioner. When requesting such approval, that person shall submit the information outlined in Appendix C of this part. If any information submitted to the Commissioner becomes invalid or outdated, the Commissioner shall be immediately notified.

(2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Commissioner:

(i) maximum rating of technique factors;

(ii) model and serial numbers of all certifiable components;

(iii) aluminum equivalent filtration of the useful beam, including any routine variation;

(iv) tube rating charts and cooling curves;

(v) records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of F.3 with the names of persons who performed such services. In addition, records of the qualifications of persons performing surveys and calibrations must be maintained. (Criteria for designation as a qualified expert are contained in Appendix D of this part).

(vi) a scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual is such areas. In addition, the drawing shall include:

(a) the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or

(b) the type and thickness of materials, or lead equivalency, of each protective barrier; and

(vii) a copy of all correspondence with the Commissioner regarding that x-ray system.

(3) Information to be Submitted to the Commissioner. The registrant shall submit to the Commissioner a copy of all surveys and calibrations performed by a Qualified Expert within sixty days of completion of the survey or calibration.

(4) X-ray Log. Each facility shall maintain an x-ray log or other record-keeping device containing the patients' names, type of examination performed, and the date of the examination.

(b) Plan Review.

(1) The Commissioner may require any registrant to utilize the services of a qualified expert to determine the shielding requirements necessary to achieve compliance with Part D of these regulations.

(2) The approval of such plans shall not perclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in D.101, D.104, and D.105 of these regulations.

(c) Certified Components or Systems. Certified x-ray components or systems shall be manufactured and assembled in accordance with the provisions set forth in 21 CFR Subchapter J.

(v) after the radiation output of the x-ray tube has been affected by the opening of any door referred to in F.8(b)(4)(iii), it shall be possible to restore the x-ray system to full operation only upon:

(a) closing the door; and subsequently,

(b) reinitiating the exposure at the control panel.

(c) Surveys, Calibrations, Spot Checks, and Operating Procedures.

(1) Surveys.

(i) All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a Qualified Expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(ii) The expert shall report his findings in writing to the person in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the Commissioner.

(iii) The survey and report shall indicate all instances where the installation in the opinion of the Qualified Expert is in violation of applicable regulations and cite all items of non-compliance.

(2) Calibrations.

(i) The calibration of an x-ray system shall be performed before it is initially put into use and at intervals not to exceed one year thereafter. It shall also be performed after any change or replacement of components which could cause a change in the radiation output or after any change in location.

(ii) The calibration of the radiatin output of the x-ray system shall be performed by or under the direction of a Qualified Expert who is physically present at the facility during such calibration.

(iii) Calibration of the radiation output of an x-ray system shall be performed with a calibrated instrument. The calibration of such instrument shall be directly traceable to a national standard. The instrument shall have been calibrated within the preceding 2 years.

(iv) The calibrations made pursuant to F.8(c)(2) shall be such that the dose at a reference point in soft tissue can be calculated to within $\pm$ 5 percent.

(v) The calibration of the x-ray system shall include, but not be limited to, the following determiantions:

(a) verification that the x-ray system is operating in compliance with the design specifications;

(b) the exposure rates for each combination of field size, technique factors, filter, and treatment distance used;

(c) the degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

(d) an evaluation of the uniformity of the radiation field symmetry.

(vi) Records of calibration performed pursuant to F.8(c)(2) shall be maintained by the registrant for 2 years after completion of the calibration.

(vii) A copy of the most recent x-ray system calibration shall be available for use by the operator at the control panel.

(3) Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

(i) the spot check procedures shall be in writing and shall have been developed by a Qualified Expert;

(ii) the measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the x-ray system;

(iii) the spot-check procedure shall be performed once or more each month;

(iv) the procedure shall also note conditions which shall require that the system be recalibrated in accordance with F.8(c)(2); and

(v) records of spot-check measurements performed pursuant to F.8(c)(3) shall be maintained by the registrant for 2 years following such measurements.

(4) Operating Procedures.

(i) Therapeutic x-ray systems shall not be left unattended unless the system is secured pursuant to F.8(a)(10)(v).

APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Commissioner approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where appicable, the names and addresses of agents within this State.

2. Diseases or conditions for which the x-ray examinations are to be used.

3. Description in detail of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a Qualified Expert of the x-ray system(s) to be used in the screening program. The evaluation by the Qualified Expert shall show that such system(s) do satisfy all requirements of these regulations.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

APPENDIX D

Criteria for Designation as a Qualified Expert

The registrant or licensee shall determine if a person is an expert qualified by training and experience to perform radiation safety and performance surveys on diagnostic x-ray machines or calibrations of therapeutic x-ray machines and teletherapy machines according to the following criteria. In order to maintain designation as a Qualified Expert, the individual must maintain satisfactory performance of work performed in that capacity. The Commissioner shall disqualify individuals from this designation for just cause provided that a show-cause hearing has been held and the Commissioner has determined that the individual has demonstrated unsatisfactory performance as a Qualified Expert.

1. Qualified Expert, Diagnostic X-ray. The person must have knowledge and training to measure ionizing radiation, evaluate safety techniques, and advise regarding radiation protection needs to assure compliance with Virginia Rules and Regulations for Ionizing Radiation as evidenced by one or more of the following:

   a) Certification by one of the following:

      1) American Board of Radiology
      2) American Board of Health Physics

   b) A Bachelor's degree in health physics, radiological physics, medical physics, or a related area and three years of full-time experience in radiation safety including at least one year in diagnostic x-ray safety. Advanced degrees in related areas may be substituted for experience on an equal time basis, except that no substitution shall be allowed for the required one year experience in diagnostic x-ray safety.

2. Qualified Expert, Therapeutic X-ray and Teletherapy Machines. The person must be qualified by training and experience to calibrate a therapeutic x-ray machine or teletherapy machine and to establish procedures for (and review the results of) spot-check measurements. One or more of the following shall serve as evidence of qualification.

   a) Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma-ray physic, or x-ray and radium physics.

   b) Has the following minimum training and experience:

      1) A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics.

      2) One year of full-time training in therapeutic radiological physics.

      3) One year of full-time experience in radiotherapy facility including personal calibration and spot-check of at least one therapeutic x-ray or teletherapy machine.

APPENDIX 4

STATEMENT FROM BUREAU OF RADIOLOGICAL HEALTH,
DEPARTMENT OF HEALTH, ON ITS X-RAY PROTECTION PROGRAM

COMMONWEALTH of VIRGINIA

C.M.G. BUTTERY, M.D.
COMMISSIONER

Department of Health
Richmond, Virginia 23219

October 29, 1986

Richard D. Morrison
Health Regulatory Boards
1601 Rolling Hills Drive
Richmond, Virginia 23229-5005

Dear Mr. Morrison:

As requested in our previous meeting we are enclosing a brief summary of the Department's x-ray regulatory program. Without going into too much detail, we hope this will address what appears to be a misconception in HB12 that no standards for x-ray safety exist or are being implemented.

If we can be of further assistance, please do not hesitate to contact us.

Sincerely,

Carl W. Armstrong

Carl W. Armstrong, M.D., Director
Division of Health Hazards Control

Enclosure

DEPARTMENT OF HEALTH X-RAY PROTECTION PROGRAM

Title 32.1-227 eq seq. of the Code of Virginia requires the Board of Health to establish and implement a program of radiation control for the protection of public health and safety. The Bureau of Radiological Health (BRH) is the organizational unit assigned within the Department of Health to implement the Board's Ionizing Radiation Rules and Regulations dealing with the regulation of x-ray equipment and facilities in the healing arts. Functions include the registration of all x-ray equipment or facilities in the State (except on Federal Installations), and a requirement for periodic inspection of equipment and safety procedures by persons designated as "Qualified Experts" or by staff members to determine compliance with radiation control regulations. State Regulations suggest qualifications which should be held by those designated by registrants as "Qualified Experts" for purposes of these regulations, but attorneys have held that sufficient authority is not contained in the statute or regulations to mandate these qualifications.

STAFF

At the present time, five staff members work in our x-ray control program. Three regional staff members whose primary duties are enforcement are located in Roanoke (Southwest Region), Vienna (Northern Region), and Virginia Beach (Eastern Region). The Central office has two staff members whose duties are shared between x-ray and other programs.

Staff members perform selected surveys representing approximately ten percent of all surveys performed, based on the following priorities: (a) employee complaints or reports of concerns or situations possibly constituting an imminent hazard to health and safety, (b) follow-up inspections on serious violations noted in reports of surveys performed by "Qualified Experts", (c) all x-ray equipment owned or operated by State or local governments, and (d) selected surveys performed for other purposes, such as quality assurance checks or special investigations.

REGISTRATION

Responsibility for registration of all x-ray equipment, as specified in the statute, rests with the owner of such equipment. Although numerous attempts over the years have been made to fulfill whatever duty the Department has to advertise and advise owners of x-ray equipment of this requirement, it is undeniable that some practitioners may not be aware of the requirement. However, Federal regulations require assemblers of new x-ray components to notify state authorities, and State regulations require vendors to notify the Department whenever used equipment is transferred within the State. One suggestion which would be helpful in making practitioners more aware of the registration requirement is to include an advisory note to that effect on their license renewal form.

Nevertheless, based on the national ratio of the number of medical or dental units with respect to population, it is believed that a reasonable percentage of existing x-ray facilities are registered.

Currently, x-ray equipment is not assigned registration numbers nor are registration decals issued. Similarly, inspection stickers or safety decals representing a determination of compliance with our regulations are not currently issued, though this is a topic of recent discussion.

SURVEYS

In addition to inspections performed by staff, others are performed periodically by private consultants called "Qualified Experts". Current regulations allow the practitioner to determine the qualifications of persons designating themselves in this category by applying the criteria presented in Appendix D of Part F of the regulations. There are presently 56 persons who have asked to be listed as "Qualified Experts". BRH maintains a list of these persons to be provided to the practitioners on request, but no endorsement or certification is implied or expressed by providing this list.

The x-ray equipment of the following types of practices is surveyed on an annual basis: **hospitals, physicians, clinics, and chiropractors.** The following are surveyed on a three year schedule: **podiatrists, dentists, and veterinarians.**

Surveys are conducted by staff members using procedures designed to determine compliance with State regulations. Certain inspections are conducted in accordance with compliance testing procedures designed to determine compliance with manufacturing and assembly standards contained in the Federal Diagnostic X-ray Performance Standard. The testing methodology and test equipment used by "Qualified Experts" is left up to their respective professional judgements.

The scope of the survey varies from the minimum data requested on the survey form to a rather extensive testing of all timer stations and various quality control measurements and modes of equipment operation. There is presently no fee for inspection by staff members, but individual requests for inspections are not honored (except those from government facilities) unless the reason for the request falls into one of the priority cases previously listed. It is our understanding that fees in the private sector range from $35.00 to $200.00 or more per survey, depending on the type and scope of services provided.

VIOLATION FOLLOW-UP

All survey results are reported on standard forms to the Central office. It is the responsibility of the registrant to return a completed survey report to BRH within 60 days of the survey; some "Qualified Experts" may automatically do this for the registrant, while others may not. Obviously, this difference may lead to confusion on the part of the registrant, and unreported surveys.

The survey reports are then reviewed by the regional staff and follow up of serious items of non-compliance is initiated by either phone calls requesting evidence of compliance or repairs, or a personal visit may be made by a staff member. The registrant is given 60 days to make correction(s). If the registrant makes no visible attempt to correct the item or request a variance then the equipment is posted regarding its non-compliant state and the case is referred through channels specified in the Administrative Process Act in order to resolve the case.

The statistics of x-ray surveys for 1984, 1985 and 1986 are presented in Table I.

TABLE I

X-RAY INSPECTION STATISTICS

1984 Staff Surveys:	SW	N	C	E	TOTAL
#Tubes Inspected	168	80	273	224	745
#of Serious Violations.	18	98	21	47	184
#Resolved	17	96	18	37	168
%Resolved	94 %	98%	86%	79 %	91%
#Nonserious	150	162	269	223	804
1985 Staff Surveys					
#Tubes Inspected	278	62	12	212	564
#of serious Violations.	137	155	1	25	318
#Resolved	106	126	0	18	250
%Resolved	77 %	83%	0%	72	79%
#Nonserious	260	147	8	202	617
1986 Staff Surveys					
#Tubes Inspected	89	86	19	124	318
#of Serious Violations	10	55	3	13	81
#Resolved	7	56	3	8	74
%Resolved	70 %	102%	100%	62	91%
#Nonserious	196	118	4	123	441
1986 Q.E. Surveys					
#Tubes Inspected	1,043	617	673	678	3,011
#Serious Violations	59	55	26	45	185
#Resolved	39	46	21	12	118
%Resolved	66%	84%	81%	27%	64%
#Nonserious	380	331	400	559	1,670
1986 Totals Combined					
#Tubes Inspected	1,132	703	692	802	3,329
#Serious	69	110	29	58	266
#Resolved	46	102	24	20	192
%Resolved	67%	93%	83%	35%	72%
#Nonserious	576	449	404	682	2,111

SW = SOUTHWEST REGION
N = NORTHERN REGION
C = CENTRAL REGION
E = EASTERN REGION

DATA AUTOMATION

BRH has recently acquired a hard disk computer system and is in the process of automating the x-ray files. The following data bases have been completed:

		Number of Facilities
a.	Physicians	852
b.	Chiropractors	171
c.	Podiatrists	123
d.	Veterinarians	223
e.	Hospitals	122

The following are data bases which are incomplete:

a.	Dentists	1400 (Estimate 3000 total)
b.	Virginia Institutions	61

Previous to the automation of our files, we were unable to keep track of facilities over-due for inspection. BRH is in the process of notifying registrants when a current survey is not on file with this office, and tracking each case until the situation is corrected. This process will take approximately six months to complete.

APPENDIX 5

LETTER FROM THE STATE HEALTH COMMISSIONER

COMMONWEALTH of VIRGINIA

C.M.G. BUTTERY, M.D.
COMMISSIONER

Department of Health
Richmond, Virginia 23219

November 26, 1986

Mr. Richard D. Morrison, Policy Analyst
Department of Health Regulatory Boards
1601 Rolling Hills Drive
Richmond, Virginia 23229-5005

Dear Mr. Morrison:

Thank you for the opportunity to review the draft report on HJR 12. I have discussed this report with Dr. Grayson Miller and while I agree with the recommendations of the study, I want to emphasize that the Department of Health cannot take on these new tasks without significant additional resources.

The Department will be able to absorb the expenses of participating in a joint task force to oversee the design and implementation of a registration program; however, the registration program itself cannot be funded from existing revenues. Estimates of total costs for this new program cannot be made until the Task Force makes recommendations for the registration process, but there will be additional costs for staff and for a computer system.

If the report is amended to reflect the need for additional resources, then it has my approval.

Please call me at 786-3561 if you would like to discuss this further.

Sincerely,

C. M. G. Buttery, M.D., M.P.H.
State Health Commissioner

cc: Ms. Deborah D. Oswalt
Edwin M. Brown, M.D.
Grayson Miller, M.D.
Ms. Sally Camp

VDH
Virginia Department of Health