

State regulatory radiation activities

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It is indeed a pleasure to have the opportunity to speak before the American Academy of Pedodontics. Your organization is to be congratulated on holding this Conference entitled *Radiation Exposure in Pediatric Dentistry*. The subject of radiation exposure of patients, of our population, and of radiation workers continues to be as timely today, as it was twenty years ago when I entered the field — and possibly even more controversial.

I'm here today representing the Conference of Radiation Control Program Directors. The Conference is an organization representing the radiation control programs of all 50 states, certain metropolitan areas of the United States, the District of Columbia, and the U.S. Territories of Puerto Rico, Guam, and the Virgin Islands. The Conference membership includes each person who directs, or has managerial responsibility for, the various state and local radiation control programs. There are 60 full members, and 100 associate members who represent the technical staff of the state and local radiation control programs.

The Conference was formed in 1968 primarily to provide a forum for communication between the various state and local programs, and between the states and the many federal agencies that have some responsibility in radiation protection. The importance of providing an avenue of good communication, so that uniform standards, regulations, guidelines, and overall safety programs will develop in the United States, is illustrated by the facts, that:

1. In addition to the 60 different major state or local radiation control programs, there are many other state or local agencies with some areas of responsibility, such as Civil Defense, environmental, labor, and other agencies. In addition, 26 state and local governments have formal agreements with the U.S. Nuclear Regulatory Commission (NRC), previously the Atomic Energy Commission, in which responsibility for the control and regulation of certain types of radioactive materials has been transferred from the NRC to the state. Therefore, as it relates to these specific types of radioactive materials, radiation protection lies with 26 state or local governments while for the other states, such responsibility

is still retained by the NRC. Thus in this area, radiation safety is divided between federal or state regulation, depending on the state in question.

2. Many agencies in the federal government have some responsibility in radiation protection. These include the Nuclear Regulatory Commission, Food and Drug Administration, Department of Energy, Environmental Protection Agency, Department of Labor, Department of Transportation, Department of Defense, and Federal Emergency and Management Agency, just to name a few.

With all these many state and federal governmental players in the field of radiation protection, it can easily be seen why a forum for constant communication is needed to assure uniformity and consistency. The Conference provides this forum. The establishment of this forum for communication has resulted in improved efficiency and reduced cost in efforts to approach radiation problems uniformly throughout the country.

In addition to this interchange between the various governmental agencies, the Conference has also established working relationships with many professional associations which have radiation protection concerns. Examples of some of these associations are the American College of Radiology, American Registry of Radiologic Technologist (ARRT), American Society of Radiologic Technologist (ASRT), American Society of Radiological Engineering, American Association of Physicists in Medicine, Society of Nuclear Medicine, and the American College of Nuclear Physicists.

The Conference accomplishes its objectives primarily by two methods. A meeting is held annually in which current and future issues, concerns, developments, and problems in radiation protection are discussed. One very important item at this annual meeting is to learn of new procedures and techniques in radiation protection technology. This meeting is attended by federal, state, and local governmental agencies with radiation protection responsibility. Many of the aforementioned professional associations also have representatives at the meeting.

The second method in working toward our goals is through the many working groups of the Conference.

There are currently 19 major working committees or task forces which work throughout the year on a variety of issues or problems. As an example, there is a committee on *Suggested State Regulations for the Control of Radiation*. This Committee is further subdivided into 11 specific working groups. These working groups have representation from both state and federal government. The purpose of these working groups is to develop suggested regulations, which, when reviewed by many outside groups and approved by the Board, are recommended to the members for adoption. The overriding major goal of the Conference is to assure that the exposure to radiation is as low as possible consistent with the benefit of the exposure.

Let's look at some statistics in radiation protection programs. As of 30 June 1980, all but one state (Wyoming) and the District of Columbia, had some type of legislative authority pertaining to the control of ionizing radiation, and 18 states had legislation for user control.

Forty-four states and the District of Columbia have implemented a regulatory program pertaining to the use of dental X-ray equipment. Three states have implemented a voluntary program in meeting safety standards, and six states have implemented a combination regulatory/voluntary effort. For FY-79, approximately 166,000 dental X-ray machines were registered with state and local radiation control programs. These registered machines represent approximately 90% of the estimated 183,000 dental machines in use.

Those states with regulatory programs have implemented inspection programs to determine compliance with adopted regulations. During FY-79, over 31,000 inspections were conducted on dental X-ray machines. These inspections include 1) measurements of machine performance and safety devices, 2) operating procedures (especially film development), and 3) operator protection and adequacy of protective barriers.

Earlier, I mentioned that 18 states had legislation for user control. Thirteen of these states require formal training for dental assistance to take radiographs. User control refers to legislative authority to place some type of requirement related to a competency determination to make radiographs. For most states, the authority to regulate user qualifications of dental equipment lies in a state Board of Dentistry. In two states (California — dental lab, and New Jersey — dental assistants) the radiation control agencies have authority and have implemented user regulatory programs. Three states — Alabama, South Dakota, and Utah — and the District of Columbia do not permit dental assistants to make radiographs.

Although only 18 states have enacted legislation providing enabling authority to regulate the user,

there appears to be more and more interest in this area by other state legislatures every year. This interest has also been demonstrated in Congress for the last several years. I feel this interest will increase as the public becomes more concerned about radiographs and will demand more assurance of the competency of those who take radiographs.

At this point, the relationship of state vs federal authority in controlling radiation should be mentioned. Mr. Barnett has just given a discussion on the role of BRH in this area. For further clarification, the Radiation Control for Health and Safety Act gives the federal Department of Health and Human Services, authority to regulate the manufacturing and assembling of X-ray equipment by adopting performance standards. Once the equipment is sold and in use, the responsibility for its proper use lies primarily with state and local government.

What are the safety standards which have been established by most state or local radiation control programs? First, I'd like to address the question of when radiographs should be made. Although there are recommendations that radiographs not be taken as a matter of routine, there are no *regulations* (and shouldn't be) established by any state radiation control program concerning this question. The need for a dental radiograph, the procedures to be employed, and the frequency of the exam can be determined only by the professional judgment of the dentist. However, the dentist must be provided with sufficient information concerning not only on the benefit, but also the risk of the exam, so that he or she can make a sound decision

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about whether the benefits outweigh the risks. To achieve this objective requires a knowledge of many technical factors involving clinical considerations as well as the biological risks of the exposure. From a public health viewpoint, the biological risk is not just limited to the patient. Since one of the biological risks from X-ray exposure is genetic risk, the total genetic pool must be considered by public health agencies in their efforts to control radiation exposures.

Although when to take a radiograph is a professional decision, and cannot be controlled by rules and regulations, there are areas that can, and must be regulated. It's a simple fact of life, that some people, even professionals, will not make a special effort or

spend money to produce the lowest exposure of the patient consistent with diagnostic needs unless required by law to do so.

Before discussing some of the specific state and local rules and regulations, I would like to read the recommendations relating to dental radiographs as adopted by the Council on Dental Materials and Devices of the American Dental Association in 1978. There are 11 recommendations.

1. Use professional judgment to determine the frequency and extent of each radiographic examination, and to determine the minimum number of film exposures that will produce the desired diagnostic information.

2. The basis for film selection should be the maximum emulsion sensitivity consistent with a good image.

3. Tissue area and volume exposed to the primary beam should not exceed the minimum coverage consistent with meeting the diagnostic requirements, and when a cylindrical collimated X-ray beam is used, the beam striking the face should not be more than 2.75 inches.

4. The X-ray machine should contain a minimum total filtration consistent with federal and state requirements. General filtration should be equivalent to 1.5 mm of aluminum up to 70 kvp, and 2.5 mm for equipment above 70 kvp.

5. Shielded open-ended cylinders or rectangular collimating devices should be used in conjunction with long cone technique. All scattered radiation should be eliminated or contained except for that occasioned by the passage of X rays through the tissues to reach the film.

6. Expose the X-ray film properly for optimal density using complete and full development time.

7. Use lead aprons on all patients to prevent unnecessary radiation of the gonads and thyroid.

8. Never hold a film in place for a patient — use a film holder if necessary.

9. Unless protective shielding is provided for the operator, the installation should be so arranged that the operator can stand at least six feet from the patient and outside the path of the useful beam. Workloads of more than 30 milliamp-minutes per week may require the use of adequately shielded screens.

10. State radiological health personnel or other qualified experts should periodically conduct radiation protection surveys including personnel monitoring and quality control of the dental office.

11. Continue education in radiology (as well as other areas of dental practice).

The above recommendations follow very closely the rules and regulations adopted by state and local radiation control programs. These rules and regulations are

based on a variety of sources. The recommendations of the National Council on Radiation Protection and Measurements (NCRP) serves as one of the more important sources for the development of regulations. In the dental area, NCRP Report #35, entitled *Dental X-Ray Protection*, is the major source of information. Other sources are: the regulations of the Nuclear Regulatory Commission which pertain only to nuclear material; recommendations of various scientific committees, such as the National Academy of Science, Biological Effects of Ionizing Radiation, or BEIR Committee; and, as important as any, the firsthand experience and training of the members of the various committees who draft the suggested state regulations.

In respect to the specific requirements for dental radiography, I will only discuss some of the major ones. First, in most states with regulatory authority, all sources of radiation must either be licensed or registered with the radiation control program. For dental X-ray machines, registration is usually required. The suggested regulations also recommend that persons who are engaged in the business of installing or servicing radiation machines should be registered.

It is the responsibility of the registrant or the registrant's agent to assure that the X-ray unit and its use meet the regulations. In most states, the penalty for willfully violating these regulations is very stringent, such as \$1,000 a day fine for each violation. Exposure of individuals shall only be for purposes authorized by a licensed practitioner of the healing arts. Exposure of individuals for training, demonstration, or general screening are prohibited.

If a person in a restricted area is likely to receive 25 percent of his or her quarterly permissible limit, such individual must be supplied with an appropriate personnel monitor. If the individual is under 18 years of age, and the exposure is likely to exceed 5% of the quarterly limit, then personnel monitoring is required.

The speed of the film or screen and film combination must be the fastest speed consistent with the diagnostic objective of the exam.

Other specific requirements for dental units include:

1. Requirements for X-ray beam filtration to remove the soft rays which would only be absorbed by the skin of the patient.
2. Requirements for tube head stability.
3. Requirements for field size limitation or beam collimation.
4. A limitation on source-to-skin distance.
5. Preset timers which must be reproducible from exposure to exposure. In fact, the entire machine must demonstrate reproducibility.
6. Location of the control, if the unit is stationary, must be located in a protected area, so the opera-

tor is required to remain in the protected area during exposure.

7. Most regulations require the use of film holding devices when the technique permits.
8. Dental Fluoroscopy is prohibited without image intensification.

A requirement now imposed by two states, Illinois and Vermont, relates to acceptable exposure limits for dental bitewing projections. In Illinois, there is a maximum and minimum exposure limit, based on the kvp of the machine. Vermont has similar exposure require-

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ments. According to the program directors in these two states, these exposure limit requirements are totally supported by the respective state dental associations. Although the limits are enforceable in these two states, the program directors have advised me that the biggest benefit of the limits are as guides in improving quality of the radiographs — once the user sees the benefits, he or she voluntarily complies. It is my opinion that such limits will be implemented by other states in the future, not only in the dental area, but in the medical area as well.

Finally, I would like to speak about another very important activity of state and local radiation control programs. Many programs have implemented or plan to implement user assistance programs. These programs include a variety of services to the user, such as sponsoring educational seminars and providing instructional literature. But more important is direct service in helping the user to improve the quality of the radiograph. An example of such a service which some of you may remember, was the DENT program. This mail-out service allowed the user to make exposures on calibrated films which were returned for analysis. The user was advised of any problem areas detected, and how such problems could be corrected.

More recently, state and local programs have become concerned with quality control procedures that are being used to assure consistent, high-quality radiographs. There are many things that can cause a radiograph to be of poor quality. Poor or inconsistent

machine performance, poor film development procedures, and poor viewing systems for the final product. Many state and local programs have implemented direct services in this area to the X-ray user — they evaluate the adequacy or inadequacy of factors that affect the quality of the radiograph, and then give advice to the user on how to implement a quality assurance program. A good quality assurance program can result in: reduction of patient exposure; reduction of retakes, thereby saving the user time and money; improvement in the quality of the radiograph; and consistency in the production of the radiographs.

In summary, the responsibility for the safe and efficacious use of the dental X-ray machine lies with the dentist. It is his or her responsibility to know the biological risks and how to apply safety devices and procedures. Various state and local radiation control agencies are charged by their state legislatures to assure that these machines are used safely, and in most cases, have provided stringent penalty for willful violation of the law.

The primary objective of state/local radiation programs and of the Conference is to assure that the patient, the public and the radiation worker receive the lowest radiation exposure consistent with the needs for a diagnostic radiograph. To accomplish this objective, the user must be efficacious in prescribing the radiograph. The need for the radiograph must always have a benefit that outweighs the risks. The X-ray equipment must meet adopted standards for radiation protection, and the procedures followed by the user must have radiation protection as a primary consideration.

The public is extremely sensitive and concerned about radiation exposure. If each X-ray user does not make a special effort to assure the efficacious and safe use of this valuable diagnostic tool, the public will demand, and state legislatures will respond to this demand, with more stringent laws and regulations requirements.

This conference demonstrates your efforts to determine safe X-ray procedures, which, when put into practice, may reduce some of the public concern and negate the need for additional laws or regulations. Again I compliment you in holding this conference, and thank you for inviting me.

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