

§ 73.20

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

§ 73.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision.

(c) The HHS Secretary's decision constitutes final agency action.

[77 FR 61115, Oct. 5, 2012]

§ 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Depart-

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mental Appeals Board have been delegated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

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APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of

Public Health Service, HHS

§ 75.2

1981, Pub. L. 97-35, 95 Stat. 599-600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§ 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.

(b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing ionizing radiation. Nothing in these accreditation standards is intended to discriminate against proprietary schools.

§ 75.2 Definitions.

All terms not defined herein shall have the meaning given them in the Act. As used in this part:

Accreditation, as applied to an educational program, means recognition, by a State government or by a nongovernmental agency or association, of a specialized program of study as meeting or exceeding certain established qualifications and educational standards. As applied to a health care or educational institution, *accreditation* means recognition, by a State govern-

ment or by a nongovernmental agency or association, of the institution as meeting or exceeding certain established standards or criteria for that type of institution.

Act means the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10001-10008.

Continuing competency means the maintenance of knowledge and skills and/or demonstrated performance that are adequate and relevant to professional practice needs.

Credentialing means any process whereby a State Government or nongovernmental agency or association grants recognition to an individual who meets certain predetermined qualifications.

Dental hygienist means a person licensed by the State as a dental hygienist.

Dental assistant means a person other than a dental hygienist who assists a dentist in the care of patients.

Educational program means a set of formally structured activities designed to provide students with the knowledge and skills necessary to enter an occupation, with evaluation of student performance according to predetermined objectives.

Energized laboratory means any facility which contains equipment that generates ionizing radiation. This does not include facilities for training students when the equipment is not powered to emit ionizing radiation, e.g., practice in setting controls and positioning of patients.

Formal training means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

Ionizing radiation means any electromagnetic or particulate radiation (X-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles) which interacts with atoms to produce ion pairs in matter.

Licensed practitioner means a licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

Licensure means the process by which an agency of State government grants permission to persons meeting predetermined qualifications to engage in an occupation.

Nuclear medicine technologist means a person other than a licensed practitioner who prepares and administers radio-pharmaceuticals to human beings and conducts *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes.

Permit means an authorization issued by a State for specific tasks or practices rather than the entire scope of practice in an occupation.

Radiation therapy technologist means a person other than a licensed practitioner who utilizes ionizing radiation-generating equipment for therapeutic purposes on human subjects.

Radiographer means an individual other than a licensed practitioner who (1) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation, and (2) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiographers are distinguished from personnel whose use of diagnostic procedures is limited to a few specific body sites and/or standard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

Radiologist means a physician certified in radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

§ 75.3 Applicability.

(a) *Federal Government*. Except as provided in section 983 of the Act, the credentialing standards set out in the Appendixes to this part apply to those individuals who administer or propose to administer radiologic procedures, in each department, agency and instrumentality of the Federal Government as follows:

(1) *Radiographer Standards* apply to all individuals who are radiographers as defined in § 75.2 and who are not practitioners excepted by the Act.

(2) *Nuclear Medicine Technologist Standards* apply to all individuals who are nuclear medicine technologists as defined in § 75.2, who perform *in vivo* nuclear medicine procedures, and who are not practitioners excepted by the Act. For purposes of this Act, any administration of radiopharmaceuticals to human beings is considered an *in vivo* procedure.

(3) *Radiation Therapy Technologist Standards* apply to all individuals who perform radiation therapy and who are not practitioners excepted by the Act.

(4) *Dental Hygienist Standards* apply to all dental hygienists who perform dental radiography.

(5) *Dental Assistant Standards* apply to all dental assistants who perform dental radiography.

(6) The following persons are deemed to have met the requirements of these standards:

(i) Persons employed by the Federal government as radiologic personnel prior to the effective date of this regulation and who show evidence of current or fully satisfactory performance or certification of such from a licensed practitioner:

(ii) Uniformed military personnel who receive radiologic training from or through the Armed Forces of the United States and who meet standards established by the Department of Defense or components thereof, provided that those standards are determined by such Department or component to offer equivalent protection of patient health and safety:

(iii) Foreign national employed by the Federal government in positions outside of the United States who show evidence of training, experience, and

competence determined by the employing agency to be equally protective of patients health and safety; and

(iv) Persons first employed by the Federal government as radiologic personnel after the effective date of this regulation who (a) received training from institutions in a State or foreign jurisdiction which did not accredit training in that particular field at the time of graduation, or (b) practiced in a State or foreign jurisdiction which did not license that particular field or which did not allow special eligibility to take a licensure examination for those who did not graduate from an accredited educational program; provided that such persons show evidence of training, experience, and competence determined by the Office of Personnel Management or the employing agency to be equally protective of patient health and safety.

(7) The following persons are exempted from these standards:

(i) Persons who are trained to perform, or perform, covered radiologic procedures in emergency situations which preclude use of fully qualified personnel; and

(ii) Students in approved training programs.

(8) A department, agency, or instrumentality of the Federal government may, after consultation with the Secretary, use alternative criteria which it determines would offer equivalent protection of patient health and safety.

(b) *States.* The States may, but are not required to, adopt standards for accreditation and credentialing that are consistent with the standards set out in the appendixes to this part.

APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIOGRAPHERS

A. Description of the Profession

The radiographer shall perform effectively by:

1. Applying knowledge of the principles of radiation protection for the patient, self, and others.

2. Applying knowledge of anatomy, positioning, and radiographic techniques to accurately demonstrate anatomical structures on a radiograph.

3. Determining exposure factors to achieve optimum radiographic technique with a minimum of radiation exposure to the patient.

4. Examining radiographs for the purpose of evaluating technique, positioning, and other pertinent technical qualities.

5. Exercising discretion and judgment in the performance of medical imaging procedures.

6. Providing patient care essential to radiologic procedures.

7. Recognizing emergency patient conditions and initiating lifesaving first aid.

B. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals;

(c) Medical schools;

(d) Postsecondary vocational/technical schools and institutions; and

(e) Other acceptable institutions which meet comparable standards.

3. The sponsoring institutions and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

C. Instructional Facilities

1. *General.* Appropriate classroom and clinical space, modern equipment, and supplies for supervised education shall be provided.

2. *Laboratory.* Energized laboratories utilized for teaching purposes shall be certified as required for compliance with Federal and/or State radiation safety regulations. The use of laboratories shall be governed by established educational objectives.

3. *Reference Materials.* Adequate up-to-date scientific books, periodicals, and other reference materials related to the curriculum and profession shall be readily accessible to students.

D. Clinical Education

1. The clinical phase of the educational program shall provide an environment for supervised competency-based clinical education and experience and offer a sufficient and well-balanced variety of radiographic examinations and equipment.

2. An acceptable ratio of students to registered technologists shall be maintained in the clinical teaching environment.

3. A clinical instructor(s), who shall be responsible for supervising students according to objectives, shall be identified for each primary clinical education center.

4. The maximum student enrollment shall not exceed the capacity recommended on the basis of volume and variety of radiographic procedures, resources, and personnel available for teaching purposes.

5. In programs where didactic and clinical experience are not provided in the same institution, accreditation shall be given only to the institution responsible for admissions, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the students in the clinical setting are educational. There shall be a uniform contract between the accredited institution and each of its affiliate hospitals, clearly defining the responsibilities and obligations of each.

E. Curriculum

1. The structure of the curriculum shall be based on not less than two calendar years of full-time study or its equivalent.

2. Instruction shall follow a planned outline that includes:

- (a) The assignment of appropriate instructional materials;
- (b) Classroom presentations, discussions and demonstrations; and
- (c) Examinations in the didactic and clinical aspects of the program.

3. All professional courses, including clinical education, must include specific curriculum content that shall include, but shall not be limited to:

- (a) Introduction to radiologic technology;
- (b) Medical ethics;
- (c) Imaging;
- (d) Radiographic processing technique;
- (e) Human structure and function;
- (f) Medical terminology;
- (g) Principles of radiographic exposure;
- (h) Radiographic procedures;
- (i) Principles of radiation protection;
- (j) Radiographic film evaluation;
- (k) Methods of patient care;
- (l) Pathology;
- (m) Radiologic physics; and
- (n) Radiation biology.

Related subjects added to the professional curriculum shall meet the requirements of the degree-granting institution.

F. Finances

Financial resources for operation of the educational program shall be assured through regular budgets, gifts, grants, endowments, or fees.

G. Faculty

1. *Program Director.* A program director shall be designated who is credentialed in ra-

diography. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiography shall not be adversely affected by educationally unrelated functions.

(a) *Minimum qualifications.* A minimum of two years of professional experience and proficiency in instructing, curriculum design, program planning, and counseling.

(b) *Responsibilities.* (1) The program director, in consultation with the medical director/advisor (G. 2.) shall be responsible for the organization, administration, periodic review, records, continued development, and general policy and effectiveness of the program.

(2) Opportunities for continuing education shall be provided for all faculty members.

2. *Medical Director/Medical Advisor*—(a) *minimum qualifications.* The medical director/medical advisor shall be a qualified radiologist, certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

(b) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for their achievement.

3. *Instructors.* All instructors shall be qualified through academic preparation and experience to teach the assigned subjects.

H. Students

ADMISSION

(a) Candidates for admission shall satisfy the following minimum requirements: Completion of four years of high school; successful completion of a standard equivalency test; or certification of equivalent education by an organization recognized by the United States Department of Education. Courses in physics, chemistry, biology, algebra, and geometry are strongly recommended.

(b) The number of students enrolled in each class shall be commensurate with the most effective learning and teaching practices and should also be consistent with acceptable student-teacher ratios.

I. Records

Records shall be maintained as dictated by good educational practices.

NOTE: Educational programs accredited by an organization recommended by the United States Department of Education are considered to have met these standards.

APPENDIX B TO PART 75—STANDARDS
FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

A. Sponsorship

Sponsorship must be by an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. The formal training in dental radiography may be a part of a total program of dental hygiene education accredited by an organization recognized by the United States Department of Education.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental hygiene education programs or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental hygienists must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental hygienists to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: Interaction of ionizing ra-

diation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: Sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Hygienists have the opportunity to develop competence in making radiographs. Faculty supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice where there is not direct supervision by faculty.

—Dental hygienists must demonstrate knowledge of radiation safety measures before making radiographs and, where possible, should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity which approved the training program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards. Under existing licensure provisions in all States, becoming a dental hygienist requires graduation from a dental hygiene education program accredited by an organization recog-

nized by the United States Department of Education. In lieu of this requirement, Alabama accepts graduation from a State-approved preceptorship program.

APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

A. Sponsorship

Sponsorship must be an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: Defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. Dental radiography training may be freestanding (as a continuing education course offered by State dental/dental auxiliary societies, or by dental/dental auxiliary education programs); or be a part of an educational program in dental assisting. Such dental assisting education programs may be accredited by an organization recognized by the United States Department of Education; or located in a school accredited by an institutional accrediting agency recognized by the United States Department of Education or approved by the State agency responsible for secondary and postsecondary education, or approved by a Federal agency conducting dental assistant education in that Agency.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental assisting education programs, or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental assistants must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental assistants to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: Historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: Solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that

Dental Assistants have the opportunity to develop competence in making radiographs. The clinical experience may be conducted in the dental office in which the Dental Assistant is employed or is serving an externship. Faculty and/or employing dentist supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice when there is not direct supervision by faculty and/or the employing dentist.

—Dental Assistants must demonstrate knowledge of radiation safety measures before making radiographs, and where possible should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys, including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity (or Federal agency where appropriate) which approves the educational program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment

must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

A. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

- (a) Community and junior colleges, senior colleges, and universities;
- (b) Hospitals and clinics;
- (c) Laboratories;
- (d) Medical schools;
- (e) Postsecondary vocational/technical schools and institutions; and
- (f) Other acceptable institutions which meet comparable standards.

3. The sponsoring institution and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

4. Responsibilities of the sponsor and each affiliate for program administration, instruction, supervision, etc., must be carefully described in written affiliation agreements.

B. Curriculum

Instruction must follow a plan which documents:

1. A structured curriculum including clinical education with clearly written syllabi which describe learning objectives and competencies to be achieved. The curriculum

shall be based on not less than one calendar year of full-time study or its equivalent.

2. The minimum professional curriculum that includes the following:

- (a) Methods of patient care;
- (b) Radiation safety and protection;
- (c) Nuclear medicine physics;
- (d) Radiation physics;
- (e) Nuclear instrumentation;
- (f) Statistics;
- (g) Radionuclide chemistry;
- (h) Radiopharmacology;
- (i) Departmental organization and function;
- (j) Radiation biology;
- (k) Nuclear medicine *in vivo* and *in vitro* procedures;
- (l) Radionuclide therapy;
- (m) Computer applications; and
- (n) Clinical practicum.

3. Assignment of appropriate instructional materials.

4. Classroom presentations, discussions, and demonstrations.

5. Supervised practice, experience, and discussions. This shall include the following:

- (a) Patient care and patient recordkeeping;
- (b) Participation in the quality assurance program;
- (c) The preparation, calculation, identification, administration, and disposal of radiopharmaceuticals;
- (d) Radiation safety techniques that will minimize radiation exposure to the patient, public, fellow workers, and self;
- (e) The performance of an adequate number and variety of imaging and non-imaging procedures; and
- (f) Clinical correlation of nuclear medicine procedures.

6. Evaluation of student's knowledge, problem-solving skills, and motor and clinical competencies.

7. The competencies necessary for graduation.

C. Resources

1. The program must have qualified program officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. The following program officials must be identified:

(a) *Program Director*—(1) *Responsibilities*. The program director of the educational program shall have overall responsibility for the organization, administration, periodic review, continued development, and general effectiveness of the program. The director shall provide supervision and coordination to the instructional staff in the academic and clinical phases of the program. Regular visits to the affiliates by the program director must be scheduled.

(2) *Qualifications*. The program director must be a physician or nuclear medicine technologist. The program director must

demonstrate proficiency in instruction, curriculum design, program planning, and counseling.

(b) *Medical Director*—(1) *Responsibilities*. The medical director of the program shall provide competent medical direction and shall participate in the clinical instruction. In multiaffiliate programs each clinical affiliate must have a medical director.

(2) *Qualifications*. The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board(s) of Nuclear Medicine, or Pathology, or Radiology, or possess suitable equivalent qualifications.

(c) *Clinical Supervisor*. Each clinical affiliate must appoint a clinical supervisor.

(1) *Responsibilities*. The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical affiliate.

(2) *Qualifications*. The clinical supervisor must be a technologist credentialed in nuclear medicine technology.

2. *Instructional Staff*—(a) *Responsibilities*. The instructional staff shall be responsible for instruction in the didactic and/or clinical phases of the program. They shall submit course outlines for each course assigned by the program director; evaluate students and report progress as required by the sponsoring institution; and cooperate with the program director in the periodic review and upgrading of course material.

(b) *Qualifications*. The instructors must be qualified, knowledgeable, and effective in teaching the subjects assigned.

(c) *Instructor-to-student ratio*. The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional development*. Accredited programs shall assure continuing education in the health profession or occupation and ongoing instruction for the faculty in curriculum design and teaching techniques.

3. Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources*. (a) *General*. Adequate classrooms, laboratories, and other facilities shall be provided.

(b) *Equipment and Supplies*. Modern nuclear medicine equipment, accurately calibrated, in working order, and meeting applicable Federal and State standards, if any, must be available for the full range of diagnostic and therapeutic procedures as outlined in the curriculum.

(c) *Reference Materials*. Reference materials appropriate to the curriculum shall be readily accessible to students.

(d) *Records*. Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources*. Instructional aids such as clinical materials, reference mate-

rials, demonstration and other multimedia materials must be provided.

D. Students

ADMISSION REQUIREMENTS

Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent. They shall have completed postsecondary courses in the following areas:

- (1) Human anatomy and physiology;
- (2) Physics;
- (3) Mathematics;
- (4) Medical terminology;
- (5) Oral and written communications;
- (6) General chemistry; and
- (7) Medical ethics.

Prerequisites may be completed during nuclear medicine training. Educational institutions such as junior colleges, universities, and technical vocational institutes may provide these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., two to four years).

E. Operational Policies

Students may not take the responsibility nor the place of qualified staff. However, students may be permitted to perform procedures after demonstrating proficiency, with careful supervision.

F. Continuing Program Evaluation

1. Periodic and systematic review of the program's effectiveness must be documented.

2. One element of program evaluation shall be the initial employment of graduates of the program.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

A. Sponsorship

1. Educational programs may be established in:

- (a) Community and junior colleges, senior colleges, and universities;
- (b) Hospitals, clinics, or autonomous radiation oncology centers meeting the criteria for major cancer management centers or meeting demonstrably equivalent standards;
- (c) Medical schools; and
- (d) Postsecondary vocational/technical schools and institutions.

2. The sponsoring institution and affiliates, if any, must be accredited by recognized agencies or meet equivalent standards. When more than one clinical education center is

used, each must meet the standards of a major cancer management center.

3. When didactic preparation and supervised clinical education are not provided in the same institution, accreditation must be obtained by the sponsoring institution for the total program. This institution will be the one responsible for admission, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the student in the clinical setting are educational. There shall be a uniform, written, affiliation agreement between the accredited institution and each clinical education center, clearly defining the responsibilities and obligations of each.

B. Curriculum

Educational programs of 24 months and 12 months or their equivalents may be developed. A 24-month program shall admit those candidates with a high school diploma (or equivalent) as outlined in D.1. The 12-month program shall be designed for those students admitted with backgrounds as outlined in D.2.

Instruction must follow a plan which documents:

1. A structured curriculum with clearly written course syllabi which describe competencies and learning objectives to be achieved. The curriculum shall include but not necessarily be limited to the following:

- (a) Orientation to radiation therapy technology;
- (b) Medical ethics and law;
- (c) Methods of patient care;
- (d) Medical terminology;
- (e) Human structure and function;
- (f) Oncologic pathology;
- (g) Radiation oncology;
- (h) Radiobiology;
- (i) Mathematics;
- (j) Radiation physics;
- (k) Radiation protection;
- (l) Radiation oncology technique;
- (m) Radiographic imaging; and
- (n) Clinical dosimetry.

The curriculum must include a plan for well-structured competency-based clinical education.

2. Assignment of appropriate instructional materials.

3. Classroom presentations, discussions, and demonstrations.

4. Supervised clinical education and laboratory practicum.

5. Evaluation of students to assess knowledge, problem-solving skills, and motor and clinical competencies.

6. Program graduates must demonstrate competencies including, but not limited to, the following:

- (a) Practice oral and written communications;

- (b) Maintain records of treatment administered;

- (c) Perform basic mathematical functions;

- (d) Demonstrate knowledge of human structure, function, and pathology;

- (e) Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;

- (f) Provide basic patient care and cardiopulmonary resuscitation;

- (g) Deliver a planned course of radiation therapy;

- (h) Verify physician's prescribed course of radiation therapy and recognize errors in computation;

- (i) Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;

- (j) Produces and utilize immobilization and beam directional devices;

- (k) Prepare commonly used brachytherapy sources;

- (l) Demonstrate knowledge of methods of calibration of equipment, and quality assurance;

- (m) Prepare isodose summations;

- (n) Detect malfunctioning equipment;

- (o) Apply rules and regulations for radiation safety, and detect defects which might pose a radiation hazard;

- (p) Understand the function of equipment and accessories;

- (q) Demonstrate knowledge of methods of continuing patient evaluation (follow up);

- (r) Apply wedge and compensating filters;

- (s) Recognize patients' clinical progress, complications, and demonstrate knowledge of when to withhold treatment until consultation with the physician; and

- (t) Interact with patients and families concerning the physical and psychological needs of patients.

C. Resources

1. *Program Officials.* The program must have a qualified program official or officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. A program director is necessary; other program officials may be required.

(a) *Program Director—(1) Responsibilities.*

—The director of the educational program shall be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiation therapy technology shall not be adversely affected by educationally unrelated functions.

—In a college-sponsored program, or a hospital-sponsored multiple affiliate program, the program director shall be an employee of the sponsoring institution. A schedule of regular affiliate visits must be maintained.

(2) *Qualifications.*

- Must be a technologist qualified in radiation therapy technology and educational methodologies.
- Must be credentialed in radiation therapy technology or possess suitable equivalent qualifications.
- Must have at least two years' experience as an instructor in an accredited educational program.

(b) *Clinical Supervisor.* Each clinical education center shall appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical education center.

(2) *Qualifications.* Must be a technologist, with suitable experience, qualified in radiation therapy technology and educational methodologies and must be credentialed in radiation therapy technology.

(c) *Medical Director/Medical Advisor—*

(1) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for achievement.

(2) *Qualifications.* The medical director/medical advisor shall be a qualified radiation oncologist certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

2. *Instructional Staff—* (a) *Responsibilities.* The instructional staff shall be responsible for submitting course outlines for each course assigned by the program director; evaluating students and reporting progress as required by the sponsoring institution; and cooperating with the program director in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be individually qualified, must be effective in teaching the subjects assigned, and must meet the standards required by the sponsoring institution.

(c) *Instructor-to-Student Ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional Development.* Programs shall have a policy that encourages continuing education in radiation therapy technology and assures ongoing instruction for the faculty in curriculum design and teaching strategies.

3. *Financial Resources.* Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources—*(a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided. All affiliated institutions shall provide space required for these facilities.

(b) *Equipment and Supplies.* Appropriate modern equipment and supplies in sufficient quantities shall be provided.

(c) *Laboratory.* Energized laboratories must meet Federal and/or State radiation and safety regulations.

(d) *Reference Materials.* An adequate supply of up-to-date books, periodicals, and other reference materials related to the curriculum and the profession shall be readily available to students.

(e) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided.

D. *Students*

ADMISSION

1. Applicants must be high school graduates (or equivalent) with an educational background in basic science and mathematics.

2. For admission to a 12-month program, the candidate must satisfy one of the following requirements:

(a) Graduation from an accredited or equivalent program in radiography.

(b) Successful completion or challenge of courses in the following prerequisite content areas:

- Radiation physics;
- Human structure and function;
- Radiation protection;
- Medical ethics and law;
- Methods of patient care;
- Medical terminology; and
- Mathematics.

(c) Successful demonstration of the following competencies:

- Practice oral and written communications;
- Perform basic mathematical functions;
- Demonstrate knowledge of human structure and function;
- Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
- Provide basic patient care and cardiopulmonary resuscitation;
- Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
- Apply rules and regulations for radiation safety, detect defects which might pose a radiation hazard, and maintain control, if a radiation accident occurs; and
- Interact with patients and families concerning patients physical and psychological needs.

E. Continuing Program Evaluation

1. A process for periodic and systematic review of the program's effectiveness must be documented and reflected in policies.

2. Program evaluation shall include the employment performance of recent graduates.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX F TO PART 75—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

A. Licensure

1. Only eligible applicants who have passed the licensure examination shall be licensed as Radiographers, Nuclear Medicine Technologists, or Radiation Therapy Technologists.

2. Licenses shall be renewed at periodic intervals.

B. Eligibility

1. For regular eligibility to take the licensure examination, applicants shall have successfully completed an accredited program of formal education in radiography, nuclear medicine technology, or radiation therapy technology.

2. Special eligibility to take the licensure examination shall be provided for applicants whose training and/or experience are equal to, or in excess of, those of a graduate of an accredited educational program.

C. Examination

A criterion-referenced examination in radiography, nuclear medicine technology, or radiation therapy technology shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The licensed Radiographer, Nuclear Medicine Technologist, or Radiation Therapy Technologist shall maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process.

The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

APPENDIX G TO PART 75—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

Currently, Dental Hygienists are credentialed through individual State licensure processes, all of which include assessment of competence in dental radiography. In all States, Dental Hygienists are required to be licensed prior to practicing. The existing State dental hygiene licensure processes meet the intent and purpose of the Consumer-Patient Radiation Health and Safety Act of 1981 and the standards for licensing Dental Hygienists in dental radiography set forth below.

A. Licensure/Permit

1. To those who have passed a licensure or designated dental radiography examination, a license or permit shall be issued by the State entity responsible for credentialing dental personnel.

2. Licenses or permits shall be renewed at periodic intervals.

B. Eligibility

1. An individual shall provide proof of graduating student status or graduation from an accredited or approved dental hygiene or dental assisting education program.

2. For dental assistants, special eligibility to take the examination shall be provided to applicants with appropriate combinations of training and/or experience.

C. Examination

A criterion-referenced examination in dental radiography shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The Dental Hygienist or Dental Assistant shall be required to maintain continuing

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competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organiza-

tion to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.