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SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1000—GENERAL

Subpart A—General Provisions

Subpart B—Statements of Policy and Interpretation

Subpart C—Radiation Protection Recommendations

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SOURCE: 38 FR 28624, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1000.1 General.

References in this subchapter J to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[50 FR 33688, Aug. 20, 1985]

§ 1000.3 Definitions.

As used in this subchapter J:

(a) *Accidental radiation occurrence* means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

(b) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh–360ss).

(c) *Chassis family* means a group of one or more models with all of the following common characteristics:

(1) The same circuitry in the high voltage, horizontal oscillator, and power supply sections;

(2) The same worst component failures;

(3) The same type of high voltage hold-down or safety circuits; and

(4) The same design and installation.

(d) *Commerce* means:

(1) Commerce between any place in any State and any place outside thereof, and

(2) Commerce wholly within the District of Columbia.

(e) *Component*, for the purposes of this part, means an essential functional part of a subassembly or of an assembled electronic product, and which may affect the quantity, quality, direction, or radiation emission of the finished product.

(f) *Dealer* means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(g) *Director* means the Director of the Center for Devices and Radiological Health.

(h) *Distributor* means a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.

(i) *Electromagnetic radiation* includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in figure 1 includes, but is not limited to, gamma rays, x-rays, ultra-violet, visible, infrared, microwave, radiowave, and low frequency radiation.

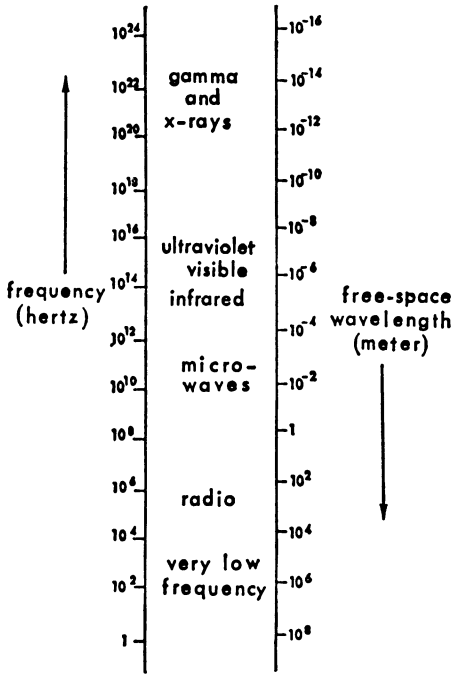

Figure 1. The Electromagnetic Spectrum

(j) *Electronic product* means:

(1) Any manufactured or assembled product which, when in operation:

(i) Contains or acts as part of an electronic circuit and

(ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

(k) *Electronic product radiation* means:

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(l) *Federal standard* means a performance standard issued pursuant to section 534 of the Federal Food, Drug, and Cosmetic Act.

(m) *Infrasonic, sonic (or audible) and ultrasonic waves* refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(n) *Manufacturer* means any person engaged in the business of manufacturing, assembling, or importing electronic products.

(o) *Model* means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

(p) *Model family* means products having similar design and radiation characteristics but different manufacturer model numbers.

(q) *Modified model* means a product that is redesigned so that actual or potential radiation emission, the manner of compliance with a standard, or the manner of radiation safety testing is affected.

(r) *Particulate radiation* is defined as:

(1) Charged particles, such as protons, electrons, alpha particles, or heavy particles, which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion; or

(2) Uncharged particles, such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation.

(s) *Phototherapy product* means any ultraviolet lamp, or product containing such lamp, that is intended for irradiation of any part of the living human body by light in the wavelength range of 200 to 400 nanometers, in order to perform a therapeutic function.

(t) *Purchaser* means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing.

(u) *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

[60 FR 48380, Sept. 19, 1995; 61 FR 13422, Mar. 27, 1996]

Subpart B—Statements of Policy and Interpretation

§ 1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which the regulations of this part apply.

(a) Examples of electronic products which may emit x-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

Ionizing electromagnetic radiation:
- Television receivers.
- Accelerators.
- X-ray machines (industrial, medical, research, educational).

Particulate radiation and ionizing electromagnetic radiation:
- Electron microscopes.
- Neutron generators.

(b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio and low frequency electromagnetic radiation include:

Ultraviolet:
- Biochemical and medical analyzers.
- Tanning and therapeutic lamps.
- Sanitizing and sterilizing devices.
- Black light sources.
- Welding equipment.

Visible:
- White light devices.

Infrared:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.

Microwave:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.
- Medico-biological heaters.
- Microwave power generating devices.
- Radar devices.
- Remote control devices.
- Signal generators.

Radio and low frequency:
- Cauterizers.
- Diathermy units.
- Power generation and transmission equipment.
- Signal generators.
- Electromedical equipment.

(c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:

Laser:
- Art-form, experimental and educational devices.
- Biomedical analyzers.
- Cauterizing, burning and welding devices.
- Cutting and drilling devices.
- Communications transmitters.
- Rangefinding devices.

Maser:
- Communications transmitters.

(d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit include:

Infrasonic:
- Vibrators.

Sonic:
Electronic oscillators.
Sound amplification equipment.
Ultrasonic:
Cauterizers.
Cell and tissue disintegrators.
Cleaners.
Diagnostic and nondestructive testing equipment.
Ranging and detection equipment.

Subpart C—Radiation Protection Recommendations

§ 1000.50 Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used without interfering with the objectives of the examination to protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within or are in close proximity to the x-ray field. Such shielding should be provided when the following conditions exist:

(a) The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation. Except as provided in paragraph (b) or (c) of this section:

(1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;

(2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film;

(3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues and could adversely affect the quality of the radiograph; and

(4) Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by 0.25 millimeter of lead.

(b) The clinical objectives of the examination will not be compromised.

(1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within 5 centimeters of its edge. It is not always possible to position shields on male patients so that no bone is obscured. Therefore, if all bone structure of the pelvic area must be visualized for a particular patient, the use of shielding should be carefully evaluated. The decision concerning the applicability of shielding for an individual patient is dependent upon consideration of the patient's unique anthropometric characteristics and the diagnostic information needs of the examination.

(2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels. However, it may be possible for

practitioners to use specific area ovarian shielding during selected views in some examinations.

(c) The patient has a reasonable reproductive potential.

(1) Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.

(2) The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

EXPECTED NUMBER OF FUTURE CHILDREN VERSUS AGE OF POTENTIAL PARENT [1]

Age	Male parent	Female parent
Fetus	2.6	2.6
0 to 4	2.6	2.5
5 to 9	2.7	2.5
10 to 14	2.7	2.6
15 to 19	2.7	2.6
20 to 24	2.6	2.2
25 to 29	2.0	1.4
30 to 34	1.1	.6
35 to 39	.5	.2
40 to 44	.2	.04
45 to 49	.07	0
50 to 54	.03	0
55 to 64	.01	0
Over 65	0	0

[1] Derived from data published by the National Center for Health Statistics, ''Final Natality Statistics 1970,'' HRA 74–1120, vol. 22, No. 12, Mar. 20, 1974.

[41 FR 30328, July 23, 1976; 41 FR 31812, July 30, 1976]

§ 1000.55 Recommendation for quality assurance programs in diagnostic radiology facilities.

(a) *Applicability.* Quality assurance programs as described in paragraph (c) of this section are recommended for all diagnostic radiology facilities.

(b) *Definitions.* As used in this section, the following definitions apply:

(1) *Diagnostic radiology facility* means any facility in which an x-ray system(s) is used in any procedure that involves irradiation of any part of the human body for the purpose of diagnosis or visualization. Offices of individual physicians, dentists, podiatrists, and chiropractors, as well as mobile laboratories, clinics, and hospitals are all examples of diagnostic radiology facilities.

(2) *Quality assurance* means the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel. The determination of what constitutes high quality will be made by the facility producing the images. Quality assurance actions include both ''quality control'' techniques and ''quality administration'' procedures.

(3) *Quality assurance program* means an organized entity designed to provide ''quality assurance'' for a diagnostic radiology facility. The nature and extent of this program will vary with the size and type of the facility, the type of examinations conducted, and other factors.

(4) *Quality control techniques* are those techniques used in the monitoring (or testing) and maintenance of the components of an x-ray system. The quality control techniques thus are concerned directly with the equipment.

(5) *Quality administration procedures* are those management actions intended to guarantee that monitoring techniques are properly performed and evaluated and that necessary corrective measures are taken in response to monitoring results. These procedures provide the organizational framework for the quality assurance program.

(6) *X-ray system* means an assemblage of components for the controlled production of diagnostic images with 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. Other components that function with the system, such as image receptors, image processors, view boxes, and darkrooms, are also parts of the system.

(c) *Elements.* A quality assurance program should contain the elements listed in paragraphs (c)(1) through (10) of this section. The extent to which each element of the quality assurance program is implemented should be determined by an analysis of the facility's objectives and resources conducted by its qualified staff or by qualified outside consultants. The extent of implementation should be determined on the

basis of whether the expected benefits in radiation exposure reduction, improved image quality, and/or financial savings will compensate for the resources required for the program.

(1) *Responsibility.* (i) Responsibility and authority for the overall quality assurance program as well as for monitoring, evaluation, and corrective measures should be specified and recorded in a quality assurance manual.

(ii) The owner or practitioner in charge of the facility has primary responsibility for implementing and maintaining the quality assurance program.

(iii) Staff technologists will generally be delegated a basic quality assurance role by the practitioner in charge. Responsibility for specific quality control monitoring and maintenance techniques or quality administration procedures may be assigned, provided that the staff technologists are qualified by training or experience for these duties. The staff technologists should also be responsible for identifying problems or potential problems requiring actions beyond the level of their training. They should bring these problems to the attention of the practitioner in charge, or his or her representative, so that assistance in solving the problems may be obtained from inside or outside the facility.

(iv) In facilities where they are available, physicists, supervisory technologists, or quality control technologists should have a major role in the quality assurance program. Such specialized personnel may be assigned responsibility for day-to-day administration of the program, may carry out monitoring duties beyond the level of training of the staff technologist or, if desired by the facility, may relieve the staff technologists of some or all of their basic monitoring duties. Staff service engineers may also be assigned responsibility for certain preventive or corrective maintenance actions.

(v) Responsibility for certain quality control techniques and corrective measures may be assigned to personnel qualified by training or experience, such as consultants or industrial representatives, from outside of the facility, provided there is a written agreement clearly specifying these services.

(vi) In large facilities, responsibility for long-range planning of quality assurance goals and activities should be assigned to a quality assurance committee as described in paragraph (c)(9) of this section.

(2) *Purchase specifications.* Before purchasing new equipment, the staff of the diagnostic radiology facility should determine the desired performance specifications for the equipment. Initially, these specifications may be stated in terms of the desired performance of the equipment, or prospective vendors may be informed solely of the functions the equipment should be able to perform and asked to provide the performance specifications of items from their equipment line that can perform these functions. In either case, the responses of the prospective vendors should serve as the basis for negotiations to establish the final purchase specifications, taking into account the state of the art and balancing the need for the specified performance levels with the cost of the equipment to meet them. The final purchase specifications should be in writing and should include performance specifications. The availability of experienced service personnel should also be taken into consideration in making the final purchase decisions. Any understandings with respect to service personnel should be incorporated into the purchase specifications. After the equipment is installed, the facility should conduct a testing program, as defined in its purchase specifications, to ensure that the equipment meets the agreed upon specifications, including applicable Federal and State regulatory requirements. The equipment should not be formally accepted until any necessary corrections have been made by the vendor. The purchase specifications and the records of the acceptance testing should be retained throughout the life of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.

(3) *Monitoring and maintenance.* A routine quality control monitoring and maintenance system incorporating state-of-the-art procedures should be established and conducted on a regular schedule. The purpose of monitoring is

to permit evaluation of the performance of the facility's x-ray system(s) in terms of the standards for image quality established by the facility (as described in paragraph (c)(4) of this section) and compliance with applicable Federal and State regulatory requirements. The maintenance program should include corrective maintenance to eliminate problems revealed by monitoring or other means before they have a serious deleterious impact on patient care. To the extent permitted by the training of the facility staff, the maintenance program should also include preventive maintenance, which could prevent unexpected breakdowns of equipment and disruption of departmental routine.

(i) The parameters to be monitored in a facility should be determined by that facility on the basis of an analysis of expected benefits and cost. Such factors as the size and resources of the facility, the type of examinations conducted, and the quality assurance problems that have occurred in that or similar facilities should be taken into account in establishing the monitoring system. The monitoring frequency should also be based upon need and can be different for different parameters.

(ii) Although the parameters to be monitored will vary somewhat from facility to facility, every diagnostic radiology facility should consider monitoring the following five key components of the x-ray system:

(*a*) Film processing.

(*b*) Basic performance characteristics of the x-ray unit.

(*c*) Cassettes and grids.

(*d*) View boxes.

(*e*) Darkroom.

(iii) Examples of parameters of the above-named components and of more specialized equipment that may be monitored are as follows:

(*a*) For film processing:

An index of speed.
An index of contrast.
Base plus fog.
Solution temperatures.
Film artifact identification.

(*b*) For basic performance characteristics of the x-ray unit:

(*1*) For fluoroscopic x-ray units:

Table-top exposure rates.
Centering alignment.
Collimation.
kVp accuracy and reproducibility.
mA accuracy and reproducibility.
Exposure time accuracy and reproducibility.
Reproducibility of x-ray output.
Focal spot size consistency.
Half-value layer.
Representative entrance skin exposures.

(*2*) For image-intensified systems:

Resolution.
Focusing.
Distortion.
Glare.
Low contrast performance.
Physical alignment of camera and collimating lens.

(*3*) For radiographic x-ray units:

Reproducibility of x-ray output.
Linearity and reproducibility of mA stations.
Reproducibility and accuracy of timer stations.
Reproducibility and accuracy of kVp stations.
Accuracy of source-to-film distance indicators.
Light/x-ray field congruence.
Half-value layer.
Focal spot size consistency.
Representative entrance skin exposures.

(*4*) For automatic exposure control devices:

Reproducibility.
kVp compensation.
Field sensitivity matching.
Minimum response time.
Backup timer verification.

(*c*) For cassettes and grids:

(*1*) For cassettes:

Film/screen contact.
Screen condition.
Light leaks.
Artifact identification.

(*2*) For grids:

Alignment and focal distance.
Artifact identification.

(*d*) For view boxes:

Consistency of light output with time.
Consistency of light output from one box to another.
View box surface conditions.

(*e*) For darkrooms:

Darkroom integrity.
Safe light conditions.

(*f*) For specialized equipment:

(*1*) For tomographic systems:

Accuracy of depth and cut indicator.

Thickness of cut plane.
Exposure angle.
Completeness of tomographic motion.
Flatness of tomographic field.
Resolution.
Continuity of exposure.
Flatness of cassette.
Representative entrance skin exposures.

(*2*) For computerized tomography:

Precision (noise).
Contrast scale.
High and low contrast resolution.
Alignment.
Representative entrance skin exposures.

(iv) The maintenance program should include both preventive and corrective aspects.

(*a*) *Preventive maintenance.* Preventive maintenance should be performed on a regularly scheduled basis with the goal of preventing breakdowns due to equipment failing without warning signs detectable by monitoring. Such actions have been found cost effective if responsibility is assigned to facility staff members. Possible preventive maintenance procedures are visual inspection of the mechanical and electrical characteristics of the x-ray system (covering such things as checking conditions of cables, watching the tomographic unit for smoothness of motion, assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom, and listening for unusual noises in the moving parts of the system), following the manufacturer's recommended procedures for cleaning and maintenance of the equipment, and regular inspection and replacement of switches and parts that routinely wear out or fail. The procedures included would depend upon the background of the staff members available. Obviously, a large facility with its own service engineers can do more than an individual practitioner's office.

(*b*) *Corrective maintenance.* For maximum effectiveness, the quality assurance program should make provision, as described in paragraph (c)(5) of this section, for ascertaining whether potential problems are developing. If potential or actual problems are detected, corrective maintenance should be carried out to eliminate them before they cause a major impact on patient care.

(4) *Standards for image quality.* Standards of acceptable image quality should be established. Ideally, these should be objective, e.g., acceptability limits for the variations of parameter values, but they may be subjective, e.g., the opinions of professional personnel, in cases where adequate objective standards cannot be defined. These standards should be routinely reviewed and redefined as needed, as described in paragraph (c)(10) of this section.

(5) *Evaluation.* The facility's quality assurance program should include means for two levels of evaluation.

(i) On the first level, the results of the monitoring procedures should be used to evaluate the performance of the x-ray system(s) to determine whether corrective actions are needed to adjust the equipment so that the image quality consistently meets the standards for image quality. This evaluation should include analysis of trends in the monitoring data as well as the use of the data to determine the need for corrective actions on a day-by-day basis. Comparison of monitoring data with the purchase specifications and acceptance testing results for the equipment in question is also useful.

(ii) On the second level, the facility quality assurance program should also include means for evaluating the effectiveness of the program itself. Possible means include ongoing studies of the retake rate and the causes of the repeated radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiographs being produced, occurrence and reasons for complaints by radiologists, and analysis of trends in the results of monitoring procedures such as sensitometric studies. Of these, ongoing studies of the retake rate (reject rate) and its causes are often the most useful and may also provide information of value in the first level of evaluation. Such studies can be used to evaluate potential for improvement, to make corrections, and to determine whether the corrective actions were effective. The number of rejects should be recorded daily or weekly, depending on the facility's analysis of its needs. Ideally, the reasons for the rejection

should also be determined and recorded. Should determining these reasons be impossible on a regular basis with the available staff, the analysis should be done for a 2-week period after major changes have occurred in diagnostic procedures or the x-ray system and at least semi-annually.

(6) *Records.* The program should include provisions for the keeping of records on the results of the monitoring techniques, any difficulties detected, the corrective measures applied to these difficulties, and the effectiveness of these measures. The extent and form of these records should be determined by the facility on the basis of its needs. The facility should view these records as a tool for maintaining an effective quality assurance program and not view the data in them as an end in itself but rather as a beginning. For example, the records should be made available to vendors to help them provide better service. More importantly, the data should be the basis for the evaluation and the reviews suggested in paragraphs (c)(5) and (10) of this section.

(7) *Manual.* A quality assurance manual should be written in a format permitting convenient revision as needed and should be made readily available to all personnel. The content of the manual should be determined by the facility staff, but the following items are suggested as providing essential information:

(i) A list of the individuals responsible for monitoring and maintenance techniques.

(ii) A list of the parameters to be monitored and the frequency of monitoring.

(iii) A description of the standards, criteria of quality, or limits of acceptability that have been established for each of the parameters monitored.

(iv) A brief description of the procedures to be used for monitoring each parameter.

(v) A description of procedures to be followed when difficulties are detected to call these difficulties to the attention of those responsible for correcting them.

(vi) A list of the publications in which detailed instructions for monitoring and maintenance procedures can be found. Copies of these publications should also be readily available to the entire staff, but they should be separate from the manual. (Publications providing these instructions can usually be obtained from FDA or private sources, although the facility may wish to make some modifications to meet its needs more effectively.)

(vii) A list of the records, with sample forms, that the facility staff has decided should be kept. The facility staff should also determine and note in the manual the length of time each type of record should be kept before discarding.

(viii) A copy of each set of purchase specifications developed for new equipment and the results of the acceptance testing for that equipment.

(8) *Training.* The program should include provisions for appropriate training for all personnel with quality assurance responsibilities. This should include both training provided before the quality assurance responsibilities are assumed and continuing education to keep the personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors, either in the facility or in a special program, is the most desirable type of training. The use of self-teaching materials can be an adequate substitute for supervised instruction, especially in continuing education programs, if supervised instruction is not available.

(9) *Committee.* A facility whose size would make it impractical for all staff members to meet for planning purposes should consider the establishment of a quality assurance committee whose primary function would be to maintain lines of communication among all groups with quality assurance and/or image production or interpretation responsibilities. For maximum communication, all departments of the facility with x-ray equipment should be represented. The committee may also be assigned policy-making duties such as some or all of the following:

Assign quality assurance responsibilities; maintain acceptable standards of quality; periodically review program effectiveness, etc. Alternatively, the

duties of this committee could be assigned to an already-existing committee such as the Radiation Safety Committee. In smaller facilities, all staff members should participate in the committee's tasks. The Quality Assurance Committee should report directly to the head of the radiology department, or, in facilities where more than one department operates x-ray equipment, to the chief medical officer of the facility. The committee should meet on a regular basis.

(10) *Review.* The facility's quality assurance program should be reviewed by the Quality Assurance Committee and/or the practitioner in charge to determine whether its effectiveness could be improved. Items suggested for inclusion in the review include:

(i) The reports of the monitoring and maintenance techniques to ensure that they are being performed on schedule and effectively. These reports should be reviewed at least quarterly.

(ii) The monitoring and maintenance techniques and their schedules to ensure that they continue to be appropriate and in step with the latest developments in quality assurance. They should be made current at least annually.

(iii) The standards for image quality to ensure that they are consistent with the state-of-the-art and the needs and resources of the facility. These standards should be evaluated at least annually.

(iv) The results of the evaluations of the effectiveness of the quality assurance actions to determine whether changes need to be made. This determination should be made at least annually.

(v) The quality assurance manual should also be reviewed at least annually to determine whether revision is needed.

[44 FR 71737, Dec. 11, 1979]

§ 1000.60 Recommendation on administratively required dental x-ray examinations.

(a) The Food and Drug Administration recommends that dental x-ray examinations be performed only after careful consideration of the dental or other health needs of the patient, that is, when the patient's dentist or physician judges them to be necessary for diagnosis, treatment, or prevention of disease. Administratively required dental x-ray examinations are those required by a remote third party for reasons not related to the patient's immediate dental needs. These x-ray examinations are usually a source of unnecessary radiation exposure to the patient. Because any unnecessary radiation exposure should be avoided, third parties should not require dental x-ray examinations unless they can demonstrate that such examinations provide a direct clinical benefit to the patient, and the patient's dentist or physician agrees with that assessment.

(b) Some examples of administrative x-ray examinations that should not be required by third parties are those intended solely:

(1) To monitor insurance claims or detect fraud;

(2) To satisfy a prerequisite for reimbursement;

(3) To provide training or experience;

(4) To certify qualifications or competence.

(c) This recommendation is not intended to preclude dental x-ray examinations ordered by the attending practitioner, based on the patient's history or physical examination, or those performed on selected populations shown to have significant yields of previously undiagnosed disease. This recommendation is also not intended to preclude the administrative use by third parties of dental radiographs that are taken on the order of the patient's dentist or physician as a necessary part of the patient's clinical care.

[45 FR 40978, June 17, 1980]

PART 1002—RECORDS AND REPORTS

Subpart A—General Provisions

Sec.