

§ 1000.60

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 physi-

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cian 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.

1002.1 Applicability.

1002.2 [Reserved]

1002.3 Notification to user of performance and technical data.

1002.4 Confidentiality of information.

1002.7 Submission of data and reports.