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Quality Assurance Programs for Diagnostic Radiology Facilities; Final Recommendation

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 1000

[Docket No. 76N-0145]

Quality Assurance Programs for Diagnostic Radiology Facilities

AGENCY: Food and Drug Administration.

ACTION: Final recommendation.

SUMMARY: The agency is issuing a recommendation that encourages voluntary establishment of quality assurance programs by all diagnostic radiology facilities. The recommendation suggests some aspects of the programs, but recognizes that the programs will vary with each facility's size, type, and needs. The agency wants to minimize unnecessary public exposure to electronic product radiation.

EFFECTIVE DATE: December 11, 1979.

FOR FURTHER INFORMATION CONTACT: Charles P. Froom, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 28, 1978 (43 FR 18207), the Food and Drug Administration (FDA) proposed to add new § 1000.55 (21 CFR 1000.55) to Subpart C—Radiation Protection Recommendations, Part 1000 of Chapter I of Title 21 of the Code of Federal Regulations. New § 1000.55 would recommend that health practitioners and others responsible for operating diagnostic radiology facilities establish quality assurance programs. Seven professional organizations, 14 representatives of government agencies (from 9 agencies), 1 processing chemicals manufacturer, 3 medical facilities, and 33 individual dentists, engineers, physicists, radiologists, technologists, and state employees submitted substantive comments. These comments and the agency's response to them follow:

Comments on the Approach Taken

1. Seven comments endorsed the voluntary approach for encouraging the implementation of quality assurance programs; three said the recommendation would eventually have to be made a regulation to be effective. One of these three suggested that, as an intermediate step, the recommendation be tested in Federal hospitals. Several other comments interpreted the publication as a proposed regulation instead of a proposed recommendation (an error that two other comments predicted would occur more generally). These comments indicated that the recommendation would require that all facilities monitor all of the parameters listed, establish all of the levels of responsibility mentioned, keep extensive records to satisfy some agency outside the facility, include in their manual all items suggested, and comply with other requirements. Some apparently also interpreted the recommendation as saying that facilities already consistently producing good quality images with minimum patient exposure would have to add the recommended actions to their existing program. They feared this would add costs to the facility without giving added benefits.

FDA emphasizes that establishing quality assurance programs in accordance with the recommendation is indeed voluntary. In § 1000.55(a) and in the definition of "diagnostic radiology facility" in § 1000.55(b), the agency attempted to make clear its belief that quality assurance programs would be beneficial in all types of diagnostic radiology facilities. In § 1000.55(c), the recommendation suggests 10 elements for this program. Proposed § 1000.55(a) stated, however, that the extent to which each element of a quality assurance program is implemented in a particular facility would be determined by that facility after its analysis of its objectives and resources. Especially for some small facilities, the cost of implementing every suggestion might exceed the need and benefit. However, the agency believes that the savings resulting from implementing an appropriate program would, in most cases, offset the cost of the actions. Each facility is, therefore, encouraged to implement only those recommendations it believes would lead to benefits in improved image quality, reduced radiation exposure, and/or reduced costs sufficient to compensate for the costs of the action.

To highlight the flexibility enjoyed by the facility with this voluntary approach, the following changes were made in the introductory section: (1) The second sentence of § 1000.55(a) was made the second sentence of § 1000.55(c). (2) A third sentence was added to § 1000.55(c) to emphasize further the flexibility given to each facility. Some additional changes were made in the wording of the specific elements of § 1000.55(c) to emphasize that the program is voluntary. These changes are discussed in response to the comments on the specific paragraphs of the recommendations.

Comments on the Data

Several comments addressed the studies cited to support the need for and value of quality assurance programs.

2. One comment supplied information on the changes made in the pneumoconiosis compensation program since it was studied for the Department of Health, Education, and Welfare's National Institute of Occupational Safety and Health (NIOSH) by the late Dr. Dale Trout. Before participating in the current pneumoconiosis program, facilities must submit to NIOSH sample chest radiographs and a radiograph of a test object developed by Trout. These radiographs must be considered of acceptable quality for the proper classification of pneumoconiosis before NIOSH approves a facility for participation. The reader system has also been changed. C readers are no longer used, and the B readers have been expanded from members of the three major medical centers mentioned in the proposed recommendation to all physicians who have passed an examination administered by NIOSH.

As noted in the proposed recommendation, Trout found in his study that 44 percent of the certified facilities examined had 10 percent or more of their radiographs rejected by the B or the C readers, which were then being used. The total rejection rate for all facilities was 3 percent. As a result of NIOSH's efforts, in the second round of examinations only approximately 9 percent of the facilities had a rejection rate of over 10 percent. During the January 1 to September 30, 1976 period, the average rejection rate was only 0.6 percent. For the third round of examinations, NIOSH has stated that all X-ray facilities that have a rejection rate of 5 percent or more will have to be reapproved.

Because the improvement is attributed by NIOSH to their "* * * quality control requirements for equipment and expert reading for radiographic quality by B readers," comparison of the new data with the Trout results gives a "before" and "after" picture for judging the impact of quality assurance. FDA commends NIOSH and the participating facilities for their outstanding efforts in reducing unnecessary patient exposure.

3. Another comment questioned the cost savings that several studies attributed to quality assurance programs, on the ground that facilities that already had successful programs would not be able to achieve additional savings of the magnitude seen in these

studies. Referring to facilities with successful quality assurance programs, this comment argues further that "additional regulations, imposed on an effective quality assurance program would in fact raise cost."

The savings found in all the various studies were determined by comparing conditions before implementation of a quality assurance program with conditions thereafter. The FDA estimate of the cost and exposure reduction impact of nationwide quality assurance programs was likewise based on before and after conditions. Quality assurance actions implemented by facilities, with or without effective quality assurance programs already in place, will indeed involve some cost. The crucial question the facility must ask itself is, whether these actions provide sufficient benefits in terms of money savings, reduced radiation exposure, or improved image quality to compensate for the costs. If the benefits outweigh the costs, then FDA encourages the facility to undertake the quality assurance actions. The facilities involved in the studies referred to by the comment found that the money savings alone more than paid for the costs of the quality assurance program. Thus, the benefits exceeded the costs even without taking into account any benefits from reduced exposure to radiation and from improved image qualtiy.

Facilities that now have little or no quality assurance activity are likely to obtain the largest savings from establishing a quality assurance program. Facilities that have established quality assurance programs are probably doing many of the things suggested by the recommendation. The latter may achieve some additional benefits by incorporating the remaining suggestions into their program, but if additional benefits do not seem likely, then there would be no reason to increase their quality assurance efforts in the ways suggested. At any rate, the agency reemphasizes that implementation of the program is voluntary. Contrary to the comment's suggestion, no rules are being "imposed" and no "regulations" are involved.

4. Another comment criticized the use of the Nationwide Evaluation of X-Ray Trends (NEXT) data. The preamble to the proposed recommendation noted that the results of the NEXT study indicate that a "standard patient" would have received widely different exposures for the same examination in different facilities or even with different machines within the same facility. This range of exposures is as much as a factor of 100 with some of the 12 examinations considered by NEXT and at least a factor of 10 for any of the examinations. FDA suggested in the preamble to the proposal that unnecessary radiation exposure may be caused by exposure variation that could be eliminated by quality assurance. The comment argued, however, that the differences among facilities are "chiefly due to the wide variety of image receptor sensitivities and peak kilovoltages employed."

The original analysis of the NEXT data did not divide the measured exposure data into groups based on the values of the various technical factors. However, the values of certain technique factors, among them peak kilovoltage (kVp), were collected. An analysis of the effect of different techniques has been done (Bunge, et al., 1976, Midyear Symposium of the Health Physics Society), and it has been found that, even with kVp and half-value layer (HVL) limited to a narrow range, there was still a large variation in the output of the machines. For example, with a kVp range of 78 to 82 and HVL range of 2.3 to 2.7 mm of Al, the output in milliroentgens per milliampere-seconds (mR/mAs) at 12 inches varied from less than 5 to 100. Choice of kVp by the practitioner thus does not explain the wide variation in exposures from facility to facility.

FDA has concluded that machine malfunction leading to the actual kVp and mAs values deviating from the machine settings is a major contributor to the large variation in the output values. (In the NEXT system, the kVp and mAs values are recorded from the machine settings, in contrast to the exposure values, which are measured, and the HVL values, which are calculated from exposure measurements.) For example, if a practitioner chooses to set a machine at 80 kVp, this does not mean that this is the kVp actually produced. Machine malfunction would be a problem that could be minimized by an effective quality assurance program.

The other factor mentioned by the comment, "the wide variety of image receptor sensitivities," has been studied in the last 2 years with the use of an image receptor module add-on to the main NEXT system. When a sufficient number of surveys was completed, multiple regression analysis of the P/A chest projection data was carried out using the factors of kVp, HVL, relative speed of the image receptor, grid, type of processing, and mAs. It was found that these factors could account for only 50 percent of the exposure variation (Showalter, et al., *Proceedings of the Society of Photo-Optical Instrumentation Engineers*, 127:136–139). Thus, the exposure variation cannot be explained solely on the basis of the practitioner's choice of technique factor, image receptor, etc. This analysis will be continued with more examinations as sufficient data become available. At present, it supports the conclusion drawn in the preamble of the proposed recommendation, that part of the exposure variation seen by NEXT represents unnecessary patient exposure due to equipment malfunction that might be reduced or eliminated by quality assurance programs.

5. The comment referred to in paragraph 4 argued further that the mR/mAs variation was due to the method used in calculating the HVL from the NEXT measurements, not machine malfunction. The comment said the method resulted in erroneous HVL values, which accounted for the wide variation in mR/mAs found with machines with similar HVL's.

The NEXT method, which is designed to allow a rapid survey to minimize disruption of facility routine, calculates HVL using a linear least-squares fit to three exposure measurements. FDA has evaluated the potential error in HVL's however, and found that for the kVp and HVL range reported, the maximum value would not exceed 12 percent. FDA does not believe that the small potential errors in the NEXT HVL measurements can account for the wide range in output found in machines with similar kVp and HVL values. Thus, the agency still concludes that a significant part of the mR/mAs variation is due to deviation of the actual kVp and mAs values from the machine settings. Again, this is a problem that can be minimized with a quality assurance program. The agency concludes that the comment does not invalidate the use of the NEXT data for this recommendation.

6. The comment discussed in paragraphs 4 and 5 also argued that the practitioner should be free to choose whatever techniques lead to radiographs that meet the practitioner's requirements.

This comment indicates a philosophical difference with FDA. FDA agrees that the practitioner must have the latitude to select equipment and techniques that meet the practitioner's special imaging requirements. There is, however, generally a range of exposures that will produce radiographs with roughly the same quality. FDA believes that practitioners should be encouraged to choose those techniques that give the least radiation exposure. Secondly, even when a set of technique factors is shown to be appropriate for a specific imaging

task, quality assurance programs can ensure that the practitioner's equipment is actually delivering the technique values the practitioner has selected. This helps avoid the possibility that the practitioner or the practitioner's operator may repeatedly have to change the technique factors (usually toward higher exposures) due to the decreasing ability to get a satisfactory image with the old values.

7. Another comment criticized the NIOSH and Pennsylvania Blue Shield studies because, in its view, the "vast majority" of problems revealed by these studies "were due to human error" and, therefore, would be unaffected by an equipment quality assurance program.

In the NIOSH study, Trout simply listed the problems he found, without indicating their relative magnitudes. Some were probably due to human error and some to equipment malfunction, but there was no basis for concluding that either category was responsible for a "vast majority" of the problems. However, the later data from this study indicate that, regardless of the source of the problems, the quality assurance program was effective in solving many of the problems identified.

The Blue Shield study did provide a breakdown of the reasons for judging the submitted radiographs to be unsatisfactory. A little over 30 percent of the submitted radiographs were rejected for reasons that were probably due to human error. However, another approximately 20 percent of the submitted radiographs were rejected for reasons that were probably due to equipment malfunction. Once again, equipment malfunction was proven not to be an insignificant problem.

FDA agrees that "people errors" lead to unsatisfactory radiographs and unnecessary patient exposure. But this does not mean that the equipment problems can be ignored. FDA has launched or is developing several programs in the "people" areas, but the agency is also supporting quality assurance programs to deal with equipment problems. Quality assurance actions may also help solve some of the "people" problems. For example, evaluation measures such as retake analysis can help identify operator performance problems. Identification is, of course, the first step in solving the problem.

8. The comment referred to in paragraph 7 also criticized the NIOSH and Blue Shield studies as not reflecting the general practice of radiology because they are limited only to pneumoconiosis and dental examinations.

FDA did not present the studies as representative of the total field, but only as an indication of problems in certain specialties. A study by a major film company of more than 150 general radiographic facilities was presented as evidence that the problems found with pneumoconiosis and dental examinations might be present in all types of facilities (Reference 3 in the April 28, 1978 proposal). This study found an average retake rate of 9 percent and an average rejection rate of 13 percent in facilities without quality assurance programs. (The difference between the 9 and 13 percent is partly due to blank films and is also probably partly due to radiographs that were not repeated because other views gave adequate information.) When the facilities established quality assurance programs, they were able to reduce their average rejection rate to 7 percent.

9. The same comment criticized the use of the film company study by noting that the retake rate of 9 percent of the radiographs due to unsatisfactory quality was close to twice that found in previous studies. The comment suggested that the lower retake rate was more representative of national experience than the 9 percent rate.

This assertion is not well founded. Comprehensive studies have not been done. However, the film company study, which examined more than 150 facilities, shows that many hospitals have higher rates. In contrast, the studies relied on in the comment in most cases included only 1 or 2 facilities, a slim basis on which to estimate representative conditions for the nation. In addition, the authors of at least two of the studies cited by the comment indicated their retake rates were probably underestimated (perhaps by as much as 100 percent in one case) due to various factors including lack of technologist cooperation.

10. The same comment also criticized the agency's estimate in its environmental impact analysis report (Ref. 11 in the proposal) of the dose savings impact of quality assurance programs in terms of a total national figure (209,000 to 333,000 rems of active bone marrow dose or 195,000 to 330,000 rems of whole body dose). The comment suggested instead that it would be more accurate simply to state it in terms of the percentage of per capita dose saved.

FDA believes this is simply a difference in philosophy. Physicians, such as the one who commented, treat individual patients, and the agency recognizes that per capita dose might have more meaning to them. As an agency with public health responsibilities, however, FDA must look at the impact on the genetic pool and cost of medical care for the entire population. Thus, the total nationwide savings has more meaning to the agency. It should also be noted that other groups concerned with population exposure, such as the Advisory Committee on the Biological Effects of Ionizing Radiations of the National Academy of Sciences and the United Nations Scientific Committee on the Effects of Atomic Radiation also report dose figures in terms of population dose rather than individual dose. Further, although the savings can be calculated on a per capita basis, the actual dose savings to an individual who did not have to undergo a repeated examination is far greater than the per capita savings, which is only an average figure. Thus, in this particular case the use of per capita dose savings is somewhat misleading even if the concern is with the individual rather than the entire population.

11. In another criticism of the supporting references, the same comment questioned the figure, $37,000 per 300,000 radiographs, for the cost savings due to quality assurance at the University of Alabama at Birmingham (Reference 12 in the proposal). The comment noted that the savings reported were $27,000 per 300,000 radiographs.

The $27,000 figure represented the savings using the discount prices for supplies purchased by the University of Alabama. The $37,000 figure was obtained by using the retail prices. Because discounts vary from facility to facility, the agency believes that retail prices should be used for a fair comparison. Using retail prices, the University of Alabama staff reported an average annual savings in supply costs of $67,566 after quality assurance was initiated. From this the FDA staff substracted the reported annual quality assurance labor costs of $27,625, the estimated $1,500 a year for supplies for the quality assurance program, and $1,500 for the prorated cost of the quality assurance equipment to obtain an annual savings of approximately $37,000. Because the annual workload at the University of Alabama is approximately 300,000 radiographs, the savings were expressed as $37,000 per 300,000 radiographs.

12. The comment further criticized the agency's use of the Alabama data because, according to the comment, the authors of the study stated that had their department been better organized at the outset, such large savings as they report would not have been possible.

The comment's concern is apparently based on a narrower definition of

quality assurance than that used by FDA. FDA believes that quality assurance is not limited to taking physical measurements or repairing equipment but is fundamentally a matter of good departmental management. This is one reason why the recommendation is primarily concerned with administration. If implementation of a quality assurance program stimulates or permits an improvement in the general organization of the department (as apparently occurred at the University of Alabama), then the savings from that improvement in organization should be credited to the quality assurance program. This belief is supported by the Alabama authors in their statement that: "The abrupt difference between the 1971–2 and 1972–3 fiscal years is attributed to the implementation of the main aspects of the quality assurance program."

Comments on the Paragraphs of the Recommendation

Many comments focused on one or more of the paragraphs of the proposed recommendation. For each of these paragraphs, the comments are presented, and FDA's reply to them is given.

Applicability

13. The comments addressing § 1000.55(a) chiefly concerned the application of the recommendation to small facilities. Two comments stressed that small facilities should be included. In contrast, one comment said that the major emphasis should be put on the large facilities because their example would stimulate small facilities to join the quality assurance effort. Six comments said that assistance would be needed by small facilities in implementing these programs. Their suggestions as to the nature of the assistance needed ranged from a request to prescribe a program specifically for small facilities to the establishment of regional quality assurance consulting centers. Finally, three comments said it would be impossible for small facilities to implement a quality assurance program as described in the recommendation. This belief seemed to stem in part at least from interpreting the recommendation as having to be implemented verbatim.

FDA recognizes that quality assurance programs for small facilities would be quite different from those for large facilities. For example, a committee such as that described in § 1000.55(c)(9), would obviously be valuable only for larger facilities. All facilities, small or large, are also encouraged to modify FDA's other general suggestions to meet their specific needs where necessary, although the agency believes that the vast majority of its recommendations are applicable to all facilities.

FDA also recognizes that most of the guidance now available on the details of quality control monitoring and maintenance is designed for large facilities. There is a need for guidance directed specifically to small facilities, especially because they do not have their own physicists and quality assurance technologists who could adapt large facility procedures to fit their needs. FDA has begun to collect information on quality assurance programs already available to small facilities. After this information is collected, additional techniques will be developed as needed, and information on both existing and new techniques will be distributed to the facilities. The comments that made suggestions as to appropriate programs for small facilities will be considered in the projects to provide aid to these facilities. FDA believes that these methods of providing assistance to small facilities should be tried before the concept of regional quality assurance consulting centers is considered further because of the expected costs of such centers.

To emphasize that FDA does not expect small facilities to duplicate the programs of large facilities, a sentence has been added at the end of § 1000.55(b)(3), the definition of a quality assurance program, specifically recognizing that any program will vary with the size and type of facility as well as other criteria.

Responsibility

14. A number of comments addressed § 1000.55(c)(1) on the assignment of responsibility for the quality assurance program and of the duties within that program.

Most of the comments addressed the suggested roles for the various segments of the staff, especially the relative roles of the practitioner in charge and of the technologists. Two comments supported the statement that the primary responsibility for the quality assurance program belonged to the medical practitioner in charge of the facility. A third comment implicitly agreed when it criticized the recommendation as not recognizing the importance of the trained radiologist in achieving the goal of reducing unnecessary radiation exposure. In contrast, three other comments argued that the recommendation should give more emphasis to the importance of the staff members involved either with production of images or with maintenance of the equipment. One of these comments specifically criticized § 1000.55(c)(1)(iii) for emphasizing physicists, engineers, and radiologists to the exclusion of staff technologists. A third position was taken by a comment that opposed the entire recommendation because too much emphasis was put on monitoring by technologists rather than on preventive and corrective maintenance by trained personnel. Another comment suggested that the role of the consultants to the facility should be spelled out in more detail. In the proposed § 1000.55(c)(1)(v), it was merely suggested that in some cases it would be of value to assign certain responsibilities to consultants.

In contrast to those comments that argued for increased responsibility for one or another segment of the staff, a response from a professional organization representing a nonradiologist specialty area that makes extensive use of x-ray systems indicated that the practitioners in that area were ready to yield primary if not total responsibility for the quality assurance program to "professionals trained in radiation safety and diagnostic radiology."

Finally, two comments said § 1000.55(c)(1) should be rewritten, though only one included specific suggestions. The latter comment suggested that the responsibilities should be described to fit a program for small facilities, with the roles for specialized personnel as alternatives available to large facilities. This comment voiced concern that small facilities, on viewing the suggestion that responsibilities be assigned to personnel they could not afford, would assume that they could not conduct a quality assurance program.

FDA emphasizes its belief that there are two fundamental areas of quality assurance responsibility in facilities of all sizes, from the individual practitioner's office to the largest medical facility. First, FDA firmly believes that the owner of the equipment, or the practitioner in charge, if different from the owner, must have primary responsibility for the quality assurance program even as that individual has primary responsibility for all other aspects of the facility's activities. This is true whether the owner or practitioner in charge is a radiologist, dentist, cardiologist, or any other specialist. The owner or practitioner in charge may, especially in large facilities, delegate part or all of his or her responsibility to other staff members, but this does not relieve that individual of final responsibility. Furthermore, free and open

communication between the practitioner and his or her staff is essential to the quality assurance program. The owner or practitioner in charge cannot simply set up the program and then forget it if the program is to achieve maximum success.

Second, FDA recognizes that the staff technologists will play a major role in the execution of the program. In a small facility, staff technologists may often be responsible for all the monitoring and maintenance performed by the facility and may also be responsible for recommending when outside help should be called in for more complex monitoring and maintenance. In a larger facility, staff physicists, quality assurance technologists, service engineers, or supervisory technologists may assume much of the quality assurance monitoring and maintenance responsibility, but the staff technologists will always have the important role of bringing possible problems to the attention of the specialized personnel. This alerting of the specialized personnel makes possible the prompt corrective action that is essential to the quality assurance program.

FDA agrees with the comments that noted that § 1000.55(c)(1)(iii) as proposed did not properly recognize the importance of the staff technologists and maintenance personnel. Therefore, this section has been revised to remedy this deficiency. Section § 1000.55(c)(1)(iv) has also been revised to answer the concern of the comment that stated that small facilities would be discouraged by the listing of personnel they could not afford.

Although the suggestions of the comment concerning consultant duties were valuable, FDA has decided not to incorporate them into the recommendation. If more details on consultant duties were included, the duties of other quality assurance personnel should be described in more detail also. In view of the wide variety of diagnostic radiology facilities throughout the country, FDA does not believe that such a detailed description would be appropriate for the recommendation. However, the possibility of providing more detailed suggestions in future technical publications is being considered.

Purchase Specifications

15. One comment noted that one of the greatest problems of a quality assurance program is that manufacturers may simply state that their equipment will not perform within a hospital's specifications.

Section 1000.55(c)(2) recognizes that, in developing purchase specifications, the state-of-the-art should be considered and the need for a specification balanced against the cost of meeting it. If a reasonable set of purchase specifications is developed, then the problem described by the comment should disappear. The facility would deal only with vendors who are willing to meet the specifications and agree to acceptance testing to show that they are meeting the specifications.

16. Another comment on proposed § 1000.55(c)(2) warned that the radiology staff often is not consulted on the purchase of new equipment, or their recommendations are overruled for reasons of finance or convenience.

FDA hopes that the quality assurance program will create channels of communication, such as the suggested quality assurance committee, that will allow the medical and administrative staffs to reach satisfactory compromises on purchase specifications for new equipment.

17. A third comment commended the mention of the alternative of stating the specifications in terms of functional requirements. It also suggested that the availability of experienced service personnel be taken into account in writing purchase specifications.

FDA agrees with this suggestion and has inserted a sentence in § 1000.55(c)(2) to emphasize this point.

18. The same comment also expressed concern about the suggestion that acceptance of the equipment be withheld until the necessary corrections have been made by the vendor. The comment feared that a "self-appointed expert" could break the vendor by being too unreasonable.

The vendor, of course, is entitled to assure himself or herself that the specifications and channels of acceptance are not ambiguous or dependent upon the whim of members of the facility staff. Conversely, if the vendor agrees to meet certain specifications, it is reasonable to require the vendor to meet them. Withholding payment until corrections are made is obviously a powerful weapon, and FDA believes this suggestion should remain in the recommendation. It is, of course, the facility's decision whether to accept this suggestion.

19. Two comments indicated some confusion about the relationship of the purchase specifications and acceptance testing suggested for the quality assurance programs and the requirements of FDA's diagnostic X-ray equipment performance standard (21 CFR 1020.30 through 1020.32). Both comments focused on the report in the preamble to the proposed recommendation from one of the persons commenting on the May 7, 1976 notice of intent to propose the recommendations (41 FR 18863). This individual had tested 50 new rooms of equipment after the vendor had completed installation and adjustment. Not one of the rooms met the purchase specifications. One of the comments on the April 28, 1978 proposal suggested that the vendor be reported for failure to comply with FDA's diagnostic X-ray equipment performance standard, while the other suggested that this was evidence that the performance standard had failed in its mission to remedy problems of improperly performing X-ray equipment.

FDA advises that the purchase specifications suggested as part of a facility's quality assurance program are not synonymous with the requirements of the diagnostic X-ray equipment performance standard. The purchase specifications would be developed by the facility itself based upon its needs. They would most likely address parameters in addition to those minimum requirements covered by the performance standard, which is concerned with radiation safety. Even when the purchase specifications refer to parameters discussed by the performance standard, the facility might decide to put more stringent requirements on the vendor than do the regulations. Thus, the failure of a vendor to meet purchase specifications, as in the case referred to, may have little or no bearing on the question of the value of the performance standard. The incident does underline, however, the importance of not only establishing purchase specifications but of carrying out acceptance testing to see whether they are met.

Monitoring

20. One comment on proposed § 1000.55(c)(3) differed with FDA's approach by arguing that monitoring had been overemphasized greatly. It argued that it is futile to monitor the system if quality radiographs are being produced and that it is also futile to monitor if the system is failing because the failure will be obvious.

FDA disagrees that it is futile to monitor the X-ray system under either of these conditions. If the system is producing satisfactory radiographs, monitoring may still allow detection of problems that exist but have not yet grown to the point where they seriously affect image quality. Thus, if the monitoring is followed by corrective maintenance, problems can be eliminated before they adversely affect patient care. FDA does agree that, if monitoring of a particular parameter

does not reveal any change over a period of time, then it would be appropriate to reevaluate the monitoring program for that parameter.

Similarly, FDA believes that monitoring of parameters after quality control problems appear in the radiograph is of value. The comment suggested that examination of the radiograph in such cases will reveal that a problem exists without the need for monitoring. This is true, but such examination often cannot tell the source of the problem. Monitoring of the parameters and comparing the results with the values from before the problems occurred can be valuable in pinpointing the source of difficulty.

Interestingly, despite its apparent opposition to monitoring tests, the comment stated, "The quality control test can only give information which verifies that a problem does exist or which helps to pinpoint the source of the problem." This statement indicates that the comment recognized these benefits. The comment also correctly noted that testing after a service call can reveal that problems were not resolved because a "manufacturer's service personnel do not always install and maintain X-ray equipment within acceptable standards."

FDA thus has concluded that the importance of monitoring in the quality assurance program should not be deemphasized.

21. The same comment further stated that "testing can only identify a possible problem but will not provide the solution." It also asked, "what good is any test which pinpoints a problem, if there is no one available who is capable of correcting the deficiency?", a question echoed by another comment. The comment also suggested that a major cause of "technologist's apathy" noted in some quality assurance programs was the feeling that quality assurance testing was a waste of time because no one ever did anything when problems were found.

Although FDA does not agree that monitoring should be deemphasized, the agency does agree that maintenance, both preventive and corrective, is important. Preventive maintenance has been shown effective in existing programs (Nelson, et al., *Radiologic Technology*, 49:129–134), and the essential nature of corrective maintenance both to improve equipment performance and to overcome "technologists's apathy" is obvious. Although corrective maintenance has been mentioned in the Evaluation, Records, Manual, and Review elements (§ 1000.55(c) (5), (6), (7), and (10)), further emphasis should be given. Thus, § 1000.55(c)(3) has been retitled "Monitoring and Maintenance", the introduction to this element has been rewritten; and a new subdivision (iv) has been added to provide further comments on maintenance and on the need for trained service personnel.

22. Four comments on the list of possible parameters to be monitored noted that the long list might be discouraging to facilities. The comments suggested various systems for reorganizing the list, such as pointing out the general areas of importance or listing the parameters in their order of importance. Two comments made opposing suggestions: One suggested shortening the list to only key tests; the other suggested general descriptions of the specific quality assurance procedures that should be included.

The agency is concerned that two general problems hamper the reorganization or shortening of the list of parameters. The first is that the field of quality assurance is still rapidly developing, and a consensus on the relative importance of a number of the parameters does not yet exist. In addition, the wide variety of types and sizes of diagnostic radiology facilities and their equipment will probably make it impossible ever to develop a single list of parameters that apply generally to all facilities. Thus, FDA has preferred to develop as comprehensive a list as possible and to encourage the facilities to select the ones to monitor based on what is important to them. FDA has accepted the suggestion of one comment that general areas that probably should be monitored in all programs be listed. This is done in a new § 1000.55(c)(3)(ii). The old § 1000.5(c)(3)(ii) is now § 1000.55(c)(3)(iii). The introduction to § 1000.55(c)(3)(iii) has been rewritten, and the parameter list rearranged to correspond to the areas of new § 1000.55(c)(3)(ii).

23. Two comments referred to the list of parameters to be monitored as reasonable and very important, but other comments made a number of suggestions on adding or deleting parameters.

FDA has added four parameters to the list in response to these suggestions. These are "view box surface conditions", added to § 1000.55(c)(3)(iii)(*d*), "continuity of exposure" and "flatness of cassette" added to § 1000.55(c)(3)(iii)(*f*), and "representative entrance skin exposures" added to § 1000.55(c)(3)(iii) (*b*) and (*f*). In addition, suggestions that mechanical and electrical components undergo visual inspection have been added to new § 1000.55(c)(3)(iv) on maintenance. FDA did not accept suggestions that nominal voltage and latent images in intensifying screens be monitored. The comment did not provide documentation to support the belief that variations in these parameters cause problems, and FDA is unaware of any evidence that they do.

As suggested, FDA has dropped the parameter, "solution compositions" from § 1000.55(c)(3)(iii). It is now generally accepted that pH measurements of the solutions are of little value in quality assurance monitoring and that specific gravity measurements are of value only in determining whether a fresh batch of solution has been correctly mixed (and then only if the proper value is known for comparison). FDA also agrees that other methods of monitoring solution composition require a strong knowledge of chemistry and more effort than is warranted by the results.

The suggestion that focal spot measurement should be dropped until there is a consensus standard for such measurements was not accepted. FDA believes that any of the existing methods are accurate enough for quality assurance purposes as long as the same method is used consistently. FDA also did not agree that "linearity of mA stations" should be dropped. Although this measurement is perhaps covered by the monitoring of the parameters of automatic exposure control devices, it would not be covered with machines lacking these devices.

A suggestion that it was too early to establish quality assurance protocols for computed tomography (CT) systems was not accepted. It is not too early to develop an awareness that quality assurance monitoring is necessary for these devices even though the methods might require more effort. (Most CT manufacturers even provide a test device that can be used to monitor some parameters).

One comment also suggested dropping daily measurement of fixer temperature, while another suggested that with tomographic units, "thickness of cut plane," "flatness of field," and "exposure angle" could be dropped because these parameters would not change very rapidly. It appears that the disagreement is not so much with these parameters as with the frequency of monitoring. It should be noted that the frequency of monitoring of the parameters has been left to the facility to decide. Thus if the tomographic parameters do not change rapidly, semi-annual or annual monitoring of these might be sufficient, while other parameters, such as some of those involved in film processing, might have to be done daily. Similarly, the frequency of fixer temperature

monitoring could be chosen to correspond to facility needs. Facilities are encouraged to consider revision of the monitoring schedules for the different parameters as part of the evaluation and review elements.

24. Comments also suggested that the parameters "response capability" in proposed § 1000.55(c)(3)(ii)(*e*) and "accuracy of SID indictors" in proposed § 1000.55(c)(3)(ii)(*d*) are not clear.

FDA agrees and, in an effort to solve this problem, has changed these parameter names to "minimum response time" and "accuracy of SFD indicators," respectively. (With the reorganization of the parameter list mentioned above, these parameters are now under § 1000.55(c)(3)(iii)(*b*)).

25. With respect to monitoring parameters, several comments pointed out that work remains to be done on the procedures for monitoring many of them.

Fortunately, efforts are under way in both the private and public sectors to fill these gaps, and FDA will continue to encourage progress in these areas.

Standards for Image Quality

26. Three comments addressed § 1000.55(c)(4) on setting standards for image quality. Two comments remarked about the difficulty of setting standards for quality in view of the many different opinions of what constitutes adequate quality and whether that quality should be measured or be determined by "the eye of the beholder." One comment urged that, because of this, the paragraph should either be rewritten or deleted. In contrast, a third comment urged that FDA go further by helping the facilities set standards of quality and by conducting frequent inspections to ensure that the standards are met.

FDA believes that some definition of acceptable standards of image quality is essential if quality control monitoring and maintenance is to be effective. The purpose of the monitoring is to detect parameter variations that may cause or are causing image quality problems. Appropriate standards of image quality would serve as a guide to indicate when these variations have become serious enough to require corrective action.

Ideally, if the values of these parameters are kept within certain defined limits, the image quality will be acceptable. If such limits can be agreed upon, they can serve as the standards for image quality. Such objective standards may be emerging with respect to processor performance. FDA realizes, however, that, for most parameters of the x-ray system, the standards of image quality will remain subjective for some time. This is largely because of a lack of consensus among medical practitioners as to what is "good" quality, and in some cases means for measuring the relationship between parameter variation and quality may be lacking.

FDA believes that it is not now possible or desirable to develop uniform nationwide standards. Instead, the practitioners in each facility are encouraged to determine their own standards of image quality based on their training and experience and to relate these standards to system parameter values. FDA has suggested and will suggest in other publications objective standards of image quality as they become known from research and the experience of medical facilities. In the future these objective standards (or those from other sources) may become the national norm. However, even if this should occur, the implementation of these standards would still be on a voluntary basis.

In conclusion, FDA does not agree that changes in § 1000.55(c)(4) are warranted at present.

Evaluation

27. Three comments on § 1000.55(c)(5) said that the importance of reject analysis in evaluating both the total program and the individual technologist's performance should be further emphasized.

Reject analysis is referred to in § 1000.55(c)(5)(ii) as "ongoing studies of the retake rate and the causes of the repeated radiographs." FDA agrees with the comment that the emphasis should be increased to reflect the fact that reject analysis is probably the most useful evaluation method now available. Several sentences have been added to § 1000.55(c)(5)(ii) to emphasize the value of studies of the reject rate and to suggest study characteristics and frequencies.

Records

28. Many comments were received on the recordkeeping recommendations in proposed § 1000.55(c)(6). Several comments urged that FDA emphasize the importance of maintaining records by conducting inspections of them. Others interpreted the recordkeeping suggestions as regulatory requirements and opposed them as being an added burden. One comment took an intermediate position. It recognized that the proposals on recordkeeping were recommendations, but feared that states might adopt them as regulations. This might make the recordkeeping an end in itself rather than a tool for achieving improved performance.

The importance of recordkeeping cannot be overemphasized. FDA is convinced that accurate and complete records are essential for guaranteeing that necessary monitoring and maintenance have been performed, for making effective use of the equipment warranty provisions and the services of manufacturers' representatives, for aiding in future equipment selection, for planning the replacement schedule for x-ray equipment, and for evaluating the quality assurance program so that it can be modified for maximum effectiveness.

The agency recognizes, however, that the extent of the recordkeeping, just as all other aspects of the quality assurance program, should be determined by the facility itself on the basis of what is necessary for support of its program. Because recordkeeping recommendations, like all others, are voluntary, FDA inspections to enforce them would be unauthorized by law and inappropriate.

FDA shares the concern of the comment that suggested recordkeeping might become an end in itself. Obviously the purpose of keeping quality assurance records is not just to record numbers, but to collect data that can be used. These data should be used in the evaluation (§ 1000.55(c)(5)) and review (§ 1000.55(c)(10)) elements to determine whether either the equipment or the quality assurance program itself requires adjustment to ensure effective performance. Furthermore, some problems occur periodically. Therefore, records of successful past corrective actions will help to solve the problems quickly when they recur. Clear records may also be quite useful to the facility in demonstrating the need to change vendors or improve purchase specifications.

In a further response to the comments on recordkeeping, and to clarify FDA's views, § 1000.55(c)(7) has been rewritten. In response to a question raised by one comment, § 1000.55(c)(7)(vii) has also been changed to make it clear that the facility decides how long records are to be kept.

Manual

29. The several comments on § 1000.55(c)(7) generally agreed upon the importance of a manual. One comment, however, said that for its purposes a series of manuals already in use in its agency would be preferable to that suggested in the recommendation. Two other comments made opposing suggestions. One urged that some details, specifically the suggestion for a loose-leaf format, should be deleted, while the other suggested that more details, even a complete sample manual, should be provided, though not necessarily as part of the recommendation.

Facilities are encouraged to modify the recommendations to meet their own needs. Any facility or agency may use materials of a different type or content to meet the goal of keeping all concerned personnel informed about the quality assurance program and their own quality assurance responsibilities. The introduction to § 1000.55(c)(7) has been rewritten to make this clearer. The "loose-leaf" format suggestion has also been dropped. In response to the request for more detail, other FDA publications, available or planned, will provide details on some of the items suggested for the manual. A sample manual for individual practitioners may result from a project to provide guidance to small facilities, which has recently been initiated by the FDA.

Training

30. Several comments urged that the agency expand proposed § 1000.55(c)(8) both to emphasize the importance of training and to specify further its nature.

FDA does not believe that this recommendation is the place to give detailed descriptions of training requirements because these requirements are likely to change with time. However, the training element has been expanded somewhat to emphasize the need for both initial and continuing education and the value of supervised instruction.

31. Several other comments suggested training programs that FDA might initiate or support.

The agency advises that it will continue its efforts, through the production of training materials and through cooperation with professional organizations and industry, to increase the quality assurance training available.

32. Two comments in reference to § 1000.55(c)(1), asked what is meant by the term "qualified" when referring to personnel who might be assigned quality assurance duties.

Again, FDA does not believe that these recommendations provide the proper forum for a detailed list of qualifications because these might well change with time. However, § 1000.55(c)(1) has been modified by addition of the words "by training or experience" following the word "qualified" wherever it appears.

33. Another comment related to training said the recommendation did not recognize the training in radiation protection received by radiologists.

Section 1000.55(c)(1)(ii) states that the practitioner in charge of the facility has primary responsibility for the quality assurance program. If a radiologist is a staff member at the diagnostic radiology facility, that specialist will almost certainly be in charge of the facility. Thus, the recommendation does give recognition to the training received in that specialty. However, FDA does not believe that it can single out any medical specialty as being especially qualified by its general training for quality assurance duties. Although some radiologists have been very active in the quality assurance area and have pioneered in the development of quality assurance programs, FDA's information on the training of these specialists indicates that quality assurance techniques and procedures are not routinely made a part of their education or certification examinations.

Committee

34. The comments on the suggestion that a quality assurance committee (§ 1000.55(c)(9)) be established at large facilities were mixed. Some comments endorsed the idea and suggested that the membership and duties of the committee be expanded. Other comments, however, expressed fears that such a group might "throttle" or "frustrate" the program.

The recommendation to establish a committee resulted from a comment on the May 7, 1976 notice that described the success of a quality assurance committee in a facility as well as from the agency's knowledge of the value of committees in other areas. FDA still believes that a quality assurance committee can be useful in facilitating open and frequent communication among the various groups in a facility and that such communication is essential for the quality assurance program. FDA does recognize, however, that, depending upon the attitude of its membership, a committee might act to frustrate the quality assurance program. To help forestall this possibility, changes have been made in § 1000.55(c)(9) to clarify the agency's belief that any quality assurance committee should serve communications and policy-making roles rather than an operational role. The proposed recommendation recognized that small facilities would not find a committee useful. Large facilities also do not need to organize such a committee if it is believed to be unneeded or counterproductive. Also, § 1000.55(c)(9) has been reworded slightly to indicate that the facility may not wish to assign all the suggested responsibilities to the committee. Other wording changes are intended to make clear that representatives of all departments with x-ray equipment should be included, if possible, to ensure maximum communication. Also, changes have been made to indicate that the duties of the committee could be given to an already existing committee, as one comment suggested, rather than a newly established committee. All the groups involved with diagnostic radiology should be represented on that committee.

Comments Suggesting Additional Actions

35. One comment urged that an eleventh quality assurance element—on "patient exposure"—be added to the recommendation. The comment suggested that, just as § 1000.55(c)(4) suggests establishing acceptability limits for variations of image quality parameter values, a patient exposure element could contain acceptability criteria for variation in exposure for different examinations.

FDA's quality assurance activities, including the proposed recommendation, are directed at achieving optimal diagnostic x-ray equipment performance. The agency believes that such performance will lead to reduced patient exposure as well as high image quality and reduced medical costs. A separate patient exposure recommendation would significantly expand the proposed recommendations beyond their intended scope, which is limited to equipment performance. Injection of this new consideration would involve the practitioner's choice of technique factors and raise the complex question of striking the proper balance between patient exposure and image quality. For these reasons, FDA believes that the establishment of standards for patient exposure is too important and too complex to be dealt with merely as one of eleven elements in a quality assurance recommendation directed at equipment performance. Instead, FDA published in the Federal Register of August 17, 1979 (44 FR 48354) a notice of intent requesting information on a number of aspects of the patient exposure problem. This is a preliminary action to possible future recommendations dealing specifically with patient exposure.

Although FDA is not now prepared to recommend standards for patient exposure, the agency does recognize that exposure measurements may be useful in evaluating equipment performance. Thus, as noted above, the "representative entrance skin exposures" has been added to the list of parameters to be considered for monitoring in § 1000.55(c)(3)(iii).

36. Several comments suggested that FDA publish recommendations or regulations in areas other than quality assurance to reduce radiation exposure. These suggestions included limitations

on the types of equipment that could be used, film-screen standards, new designs of equipment to provide for easy quality assurance testing, specification of techniques to be used, and certification programs to ensure that the owners and operators of x-ray equipment are adequately trained.

FDA appreciates these expressions of concern and will consider them in planning future programs. The agency advises that activities in cooperation with professional groups or other agencies are already being planned or are under way in some of these areas, e.g., film-screen standards and certification programs. However, inclusion of recommendations in these added areas as part of the basic quality assurance recommendation would significantly expand this recommendation beyond its intended scope. The agency believes that it is more appropriate to proceed independently in these other areas.

37. One comment suggested that patient exposure reductions could be achieved if the States were encouraged to make more frequent inspections of radiology facilities.

FDA believes that this suggestion is worthy of consideration, but it falls outside the area of a quality assurance recommendation. FDA notes, however, that the Bureau of Radiological Health has undertaken some activities designed to help solve the problem of limited resources for State inspections. The Bureau's efforts have been designed to enable the States to locate facilities with problems so that their resources may be concentrated on them. Two such efforts, the Dental Exposure Normalization Technique (DENT) and the Breast Exposure Nationwide Trends (BENT) programs, have been under way for some time. Both programs use thermoluminescent dosimeter (TLD) mailers to locate facilities with problems. These facilities are then visited by State personnel, who work with them on a voluntary, nonregulatory basis to help solve the problems. Average exposure reductions of 40 percent in dental facilities and 20 percent in mammography facilities have been achieved. Development of similar programs for other types of examinations as well as a program that could be used with facilities doing a number of types of examinations is currently under way.

38. Two comments suggested that the government establish some means of providing quality assurance services, especially for private offices.

The agency's BENT and DENT programs do provide some such services and, as discussed in paragraph 37, this concept is being expanded to other examinations. The time intervals between the BENT and DENT type of contacts, however, are too long for routine quality assurance actions. The option of setting up regional quality assurance centers, equivalent to the Regional Radiological Physics Centers, or programs through professional organizations or private facilities will be kept open. However, owing to the expense of such centers or programs, action will not be taken until the need is more clearly demonstrated.

39. Some comments suggested that FDA enlist the aid of the Joint Commission on Accreditation of Hospitals (JCAH) to encourage the adoption of quality assurance programs. Others asserted that the FDA efforts were not needed because the JCAH already "mandated" quality assurance programs.

FDA received a comment from the JCAH, which made clear its interest in quality assurance and radiation protection, and which in general endorsed the FDA approach. It does not appear that FDA suggestions for quality asssurance programs for diagnostic radiology facilities either conflict with or duplicate the JCAH efforts to encourage quality assurance in all hospital departments. FDA will continue to coordinate its efforts with those of the JCAH.

40. Three comments mentioned the problem of motivating personnel to initiate and maintain a quality control program.

FDA recognizes that this is perhaps the central problem that must be solved if the quality assurance program is to be successful. The agency believes that the first step in solving this problem is to win the support of the person in charge. Thus, through pilot tests of quality assurance techniques and through its publication program, FDA is attempting to collect and disseminate information on the benefits of quality assurance. FDA believes that this information is essential to convince the practitioner in charge, the facility administrator, and the administrative technologist initially to establish a quality assurance program. FDA is also working to disseminate information (by this recommendation, manuals, etc.) to help the program succeed in the facility once it has been implemented, for such success is the best method of motivation.

41. A conference conducted by the American College of Radiology with FDA support is planned for the fall of 1979. One comment suggested that this conference might be used to write a recommendation to replace the one proposed. The comment suggested further that this could serve as a motivating influence.

In view of the general support for the proposed recommendation, FDA has decided to proceed with publication of this final recommendation. The conference can then be devoted to its original purpose of discussing means to motivate facilities to use the recommendation and other guidance to establish quality assurance programs.

42. One comment suggested that the availability of "sources of information, consultants, and other resources" should be included for the benefit of facilities developing quality assurance programs.

FDA notes that, because such resources would be constantly changing, it would be impractical to include a list in the recommendation. FDA recognizes, however, that it may be difficult for a facility to locate the information, equipment, training, and other items needed for a quality assurance program. To assist in solving this problem, FDA published a Diagnostic Radiology Quality Assurance Catalog in the summer of 1977. The catalog contains information on available quality assurance equipment, services, training materials, and publications. A supplement to the catalog (covering the same types of items) was published in the fall of 1978. More than 12,000 copies of each of these volumes have been distributed, and FDA's Bureau of Radiological Health will continue to provide individual copies free of charge for as long as supplies last.

43. One comment suggested that "any quality control programs should stress conservation of silver and other resources vital to radiology."

FDA notes that quality assurance programs can indirectly conserve resources by reducing retakes and thus by reducing film usage, which in turn would conserve resources such as silver. FDA believes, however, that including direct conservation suggestions would be beyond the scope of this recommendation, which concerns equipment performance. This should not be interpreted as downgrading the value of the important conservation effort.

44. The agency advises that the new references cited in this final recommendation have been added to the administrative record for this matter. These references as well as those cited in the April 28, 1978 proposal are on file in the office of the FDA Hearing Clerk under Docket No. 76N-0145, and are available for public review in Rm. 4-65, 5600 Fishers Lane, Rockville, MD, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 356, 82 Stat. 1174–1175 (42 U.S.C. 263d)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), 21 CFR Part 1000 is amended in Subpart C by adding new § 1000.55, to read as follows:

§ 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 subparagraphs (1) through (10) of this paragraph. 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 through out 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 the 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 accurred 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, occurence 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 paragraph (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.

Effective date: This recommendation shall become effective December 11, 1979. However, interested persons may at any time submit written comments on the recommendation to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857. The comments will be considered in determining whether further amendments to or revisions of the

recommendation are warranted. Comments should be in four copies (except that individuals may submit single copies), identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

(Sec. 356, 82 Stat. 1174–1175 (42 U.S.C. 263d))

Dated: December 4, 1979.

Joseph P. Hile,

Acting Commissioner of Food and Drugs.

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