Quality Assurance in Diagnostic Radiology

Joy M. McLemore

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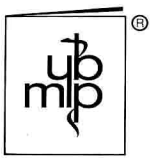
JOY M. McLEMORE, R.T.
Assistant Chief Technologist
Division of Diagnostic Radiology
Stanford University Medical Center
Stanford, California



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To the three stooges

Preface

The final recommendations from the Department of Health, Education, and Welfare for the establishment of quality assurance (QA) programs in diagnostic radiology heralds the time for all facilities to become involved in QA. These recommendations are outlined, and many are described in detail, in this book. Because the radiologist is responsible for assuring that the department meets all governmental recommendations and regulations, this may be an appropriate book for a resident training program and may serve as a reference for staff radiologists. Its intended use is primarily for students of radiologic technology and staff technologists, who will probably be those most heavily involved in the day-to-day QA activities.

Although there have been an increasing number of publications on the subject of QA, each has usually dealt with only one or two components of a comprehensive program. This fact has been a frustration for me and for many other QA technologists who have found it necessary to confer with a wide variety of specialists to piece together our own comprehensive program.

This book is an attempt to incorporate all the various specialities in order to make the task of initiating and maintaining a QA program less time consuming and more understandable.

Acknowledgments

Much, if not all, of the credit for the information in this book is due to the encouragement and support of the members of the diagnostic radiology division. Special thanks to Sandra Noon for having the foresight to invest time and assistance in establishing a quality assurance program long before it was "in style."

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JOY MCLEMORE

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Is There a Need for Quality Assurance?

FOR SEVERAL years a need for quality assurance (QA) programs in diagnostic radiology has been apparent. Efforts to establish such programs in the medical field have lagged far behind the efforts in graphic arts and in the general field of photography. Film and equipment companies have been leaders in the development of courses for diagnostic radiology personnel in the various aspects of QA. These courses, along with seminars at local, state, and national radiology meetings, have greatly increased the number of facilities participating in some form of QA programs.

The interest of radiology departments in establishing and maintaining QA programs is likely to be furthered by a report published December 11, 1979, by the Department of Health, Education, and Welfare (HEW). The study encourages the establishment of QA programs by all diagnostic radiology facilities while recognizing that the programs will vary with each facility's size, type, and needs. Although HEW emphasizes the voluntary aspect of its recommendation, the Joint Commission on Accreditation of Hospitals (JCAH) has made clear its interest in QA and radiation protection and not only has endorsed the FDA approach but also is coordinating efforts with the FDA.

Several sources have provided data indicating that many diagnostic radiology departments are producing poor-quality radiographs and are unnecessarily exposing both patients and personnel to radiation.

One study that provided data both before and after the implementation of a QA program was the National Institute of Occupational Safety and Health's (NIOSH) Pneumoconiosis Compensation Program. To participate in this program, a facility must have been certified as competent by the NIOSH by submitting sample chest radiographs, information on radiographic equipment, and qualifications of the technologists. In addition, the readers must also have been certified as competent. A radiograph from the study was read by a certified facility, (reader A) and by another radiology

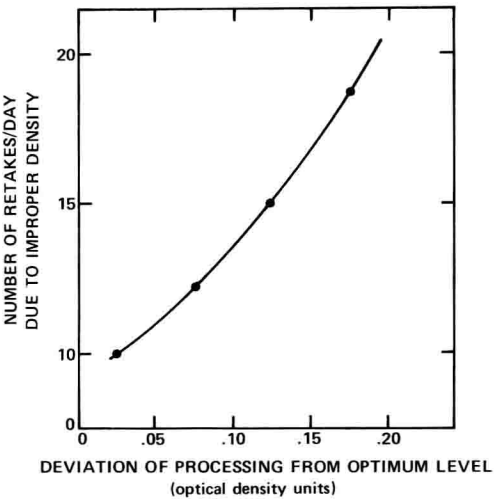

Fig 1–1.—Impact of processing variability on retake rate. (Courtesy of the Bureau of Radiologic Health, Department of Health, Education, and Welfare.)

department from one of three major medical centers (reader B). If the findings from readers A and B disagreed, then the radiograph was sent to the department chairman of one of the three medical centers (reader C) for a final decision. Despite the efforts to allow only competent facilities and readers to participate, Trout et al. found that 44% of the participating facilities had 10% to 40% of their submitted radiographs rejected by readers B and C as being of inadequate quality.

The study was repeated and this time only approximately 9% of the facilities had a rejection rate of over 10%. The improvement in the results was attributed by NIOSH to their quality control requirement for equipment and expert reading for radiographic quality by B readers.

Similar results were found with preauthorization dental radiographs submitted to Pennsylvania Blue Shield; 55.3% of the full-mouth series and 53.6% of the partial-mouth series were judged to be technically inadequate.

The Bureau of Radiologic Health (BRH), in conjunction with the radiology departments of the Public Health Service Hospital in Baltimore, showed that a QA program limited to automatic film processors reduced by 30% the number of retakes required because of poor quality of the original radiograph. One major film company reported that when QA programs were initiated for the entire facility, the rejection rate was reduced from an average of 13% to 7% (Fig 1–1).

Potential Radiation Savings

The FDA has estimated a potential nationwide reduction in patient radiation exposure with the implementation of a QA program. Depending on the number of radiographs produced, the reduction can be between 209,000 to 333,000 rems of active bone marrow dose or 195,000 to 333,000 rems of whole-body dose annually. These estimates are for reduction in hospitals alone; potential reductions owing to the implementation of QA programs in nonhospital facilities can be added to this total.

Potential Monetary Savings

In 1976, the University of Alabama at Birmingham attributed an estimated yearly savings of $37,000 over personnel costs to their QA program, amounting to a savings of approximately $12,000 per 100,000 radiographs. The bureau's Baltimore study suggested that a hospital producing 100,000 radiographs could expect to save approximately $6,000 annually from only the implementation of a processor monitoring program.

These estimates reflect film prices from several years ago and do not take into account the dramatic increase in film prices during late 1979 and early 1980. One major film company concluded that the average repeated film nationwide in October 1979 costs between $15 and $17. This figure reflects not only film and chemical prices but also such indirect costs as equipment depreciation and personnel.

HEW Recommendations

The parameters monitored may differ from one facility to the next because of the built-in flexibility of the recommendations; however, the FDA believes that every radiology facility should monitor the following five key components of the x-ray system: (1) film processing; (2) basic performance characteristics of the x-ray unit; (3) cassettes and grids; (4) view boxes; and (5) darkroom.

Examples of measures of the above-named components and of more specialized equipment that may be monitored are as follows:

1. For film processing—index of speed; index of contrast; base plus fog; solution temperatures; and film artifact identification.

2. For basic performance characteristics of the x-ray unit—tabletop exposure rates; centering alignment; collimation; peak kilovolt accuracy and reproducibility; milliampere accuracy and reproducibility; exposure time accuracy and reproducibility; reproducibility of x-ray output; consistency of focal-spot size; half-value layer; and representative entrance skin exposures.

3. For image-intensified systems—resolution; focusing; distortion; glare; low-contrast performance; and physical alignment of camera and collimating lens.

4. For radiographic x-ray units—reproducibility of x-ray output; linearity and reproducibility of milliampere stations; reproducibility and accuracy of time stations; reproducibility and accuracy of kilovolt stations; accuracy of source-to-film distance indicators; light-x-ray field congruence; half-value layer; consistency of focal-spot size; and representative entrance skin exposures.

5. For automatic exposure-control devices—reproducibility; peak kilovolt compensation; field sensitivity matching; minimum response time; and backup timer verification.

6. For cassettes—film-screen contact; screen condition; light leaks; and artifact identification.

7. For grids—alignment and focal distance and artifact identification.

8. For view boxes—consistency of light output with time; consistency of light output from one box to another; and condition of surface of view box.

9. For darkrooms—darkroom integrity and safelight conditions.

10. For specialized equipment (tomographic)—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; and representative entrance skin exposures.

11. For computerized tomography—precision (noise); contrast scale; high- and low-contrast resolution; alignment; and representative entrance skin exposures.

Many of these tests are outlined in following chapters.

Preventive Maintenance

Preventive maintenance is another area outlined in HEW's recommendations for QA programs. It should be performed regularly, with the goal of preventing breakdowns due to equipment failure. Visual inspections and such preventive maintenance procedures as checking conditions of cables and listening for unusual noises were used by HEW as examples of some items that might be checked during a preventive maintenance session. As with all components of QA, preventive maintenance sessions should be documented in detail and filed for reference by department personnel for outside agencies such as JCAH. Chapter 9 outlines specific preventive maintenance procedures for most types of radiographic equipment.

Systems maintenance logbooks can be used either in conjunction with or in place of individual report forms whenever maintenance or inspections are performed on a piece of equipment. The General Electric Company has developed an individual systems maintenance logbook that can be used for each piece of radiographic equipment. The contents include an equip-

ment list, and x-ray tube list, preventive maintenance instructions, preventive maintenance log, system modification log, government site inspection, radiation surveys, and other information of record.

Evaluation of QA Program

The evaluation of QA programs has been divided by HEW into two levels. Level 1 examines the results of the monitoring procedures. Through this information is determined whether corrective actions are needed to adjust the equipment to meet the department's standards for image quality. This evaluation also analyzes trends in the monitoring data as well as the need for corrective action on a day-to-day basis.

Level 2 evaluates the effectiveness of the QA program itself. Some of the items outlined for this level include an ongoing analysis of rejected films that examines the causes of rejected radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiographs produced, occurrence and reasons for complaints by radiologists, and analysis of trends in the results of monitoring procedures such as sensitometric studies. Analysis of rejected films can be used to evaluate potential for improvement, to make corrections, and to determine whether the corrective actions were effective.

Documentation

Provisions should be made for documenting the results of the monitoring techniques, difficulties that were detected, the corrective measures that were applied to these difficulties, and the effectiveness of the measures. The design and extent of the forms to document this information is left to the individual department to formulate. Maintenance of these records is as important as the QA procedures themselves. When the JCAH visits facilities, it wants to see the ongoing documentation of QA procedures and will not be satisfied unless the records are in writing.

QA Manual

A QA manual should be created and made available to all departmental personnel. Because the information contained in this manual will be constantly changing, a format that will accommodate convenient revision should be used. The content of the manual should be determined by each facility on the basis of its needs, but the following items have been suggested by HEW: (1) a list of the persons responsible for monitoring and maintenance techniques; (2) a list of the parameters to be monitored and the frequency of monitoring; (3) a description of the standards, criteria of quality, or limits of acceptability that have been established; (4) a brief description of the procedures to be used for monitoring each parameter; (5) a description of procedures to be followed to call any detected difficulties to the attention of those responsible for their correction; (6) a list of

publications in which detailed instructions for monitoring and maintenance procedures can be found (copies of these publications should be available to the staff); (7) a list of records, with sample forms, that the facility has decided to keep and the length of time that these records should be retained before discard; and (8) a copy of each set of purchase specifications developed for new equipment and the results of the acceptance testing for that equipment.

Training

The Department of Health, Education, and Welfare encourages provisions for appropriate training of all personnel with QA responsibilities, including training before QA responsibilities are assumed and continuing education to keep personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors is the most desirable type of training, but self-teaching materials can be an adequate substitute for supervised instruction.

QA Committee

A recommendation was also included by HEW to formulate a QA committee whose primary function would be to maintain lines of communication among all groups with QA and/or image production or interpretation responsibilities. To simplify the procedure, the functions of this committee might be assigned to a preexisting group, such as the radiation safety committee. The committee might be given policy-making duties that include all or some of the following: (1) assignment of QA responsibilities; (2) maintenance of acceptable standards of quality; and (3) periodical review of program effectiveness.

During the committee's reviewing process, the following items were included in the HEW recommendations.

1. Review the monitoring and maintenance techniques to insure that they are being performed on schedule and effectively. These reports should be reviewed at least quarterly.
2. Review the monitoring and maintenance techniques and their schedules to insure that they continue to be appropriate and in step with the latest developments in QA. They should be made current at least annually.
3. Review the standards for image quality to insure 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.
4. Review the results of the evaluation of the effectiveness of the QA actions to determine whether changes are needed. This determination should be made at least annually.
5. Review the QA manual at least annually to determine whether revision is needed.

Conclusion

The bottom line is that QA programs are here to stay. Although HEW has only strongly encouraged the establishment and maintenance of these programs, the time is fast approaching when QA will determine whether a facility will be accredited by the JCAH or similar agencies. One of the chief goals of the facility should be to become as knowledgeable as possible on the subject to insure its active participation in the formulation of future governmental rules and regulations.

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