

Diagnostic X-Ray Imaging Quality Assurance: An Overview

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Abstract

A basic diagnostic imaging quality assurance program is a regulatory requirement in many provinces^{1,2,3,4,5} and in federal institutions.¹⁰ An ineffective quality assurance program can lead to poor quality radiograms that can impair diagnosis, increase operating costs and contribute to unnecessary radiation exposure to both patients and staff. Any extension of the basic quality assurance program is the responsibility of each x-ray facility. To achieve maximum benefit, all levels of management and technical staff must support and participate in the operation of a well-defined program. This article outlines the essential aspects of a quality assurance program and is intended to encourage the review of a moderate size hospital's x-ray imaging quality assurance procedures.

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Introduction

Each year, more than 20 million diagnostic x-ray procedures are performed in Canada. Although the radiation exposure connected with these procedures cannot be avoided, there are means to reduce it as much as possible. For the protection of patients, workers and the public for example, federal and provincial government agencies enact legislation and take necessary steps to ensure that only safe and properly installed x-ray equipment is used in Canadian diagnostic x-ray facilities, for the protection of patients, workers and the public. Also, in most provinces^{1,2,3,4,5} and in federal institutions¹⁰ there is a requirement that each diagnostic x-ray facility have in place a basic quality assurance (QA) program to control the quality of diagnostic images. Any extension of the basic program is determined by the radiology department's management and QA committee.

A successful QA program requires that all staff within the radiology department understand the goals set out in the program and take an active

part in achieving its objectives. Any program lacking genuine interest from its staff and initiated only to satisfy a regulatory requirement is unlikely to produce optimal results. Meticulous care is required in the quality control of diagnostic imaging equipment to ensure good quality radiograms.

This article is divided into two parts. Part I discusses the essential aspects of a QA program recommended for implementation in a moderate-sized hospital's x-ray facilities. Part II contains detailed worksheets designed to help radiology personnel charged with reviewing their current diagnostic x-ray imaging QA procedures.

PART I

Definition

It is necessary to define, at least briefly for the purposes of this article, the general concepts of quality assurance and quality control and to review the principal objective of a radiology quality assurance program.

Quality assurance (QA) is a program used by management to maintain optimal diagnostic image quality with minimum hazard and distress to patients. The program includes periodic quality control tests, preventive maintenance procedures, administrative methods and training. It also includes continuous assessment of the efficacy of the imaging service and the means to initiate corrective action.

The primary goal of a radiology quality assurance program is to ensure the consistent provision of prompt and accurate diagnosis of patients. This goal will be adequately met by a QA program having the following three secondary objectives:

- to maintain the quality of diagnostic images;
- to minimize the radiation exposure to patient and staff; and
- to be cost effective.

Quality control (QC) consists of a series of standardized tests developed to detect changes in x-ray equipment function from its original level of performance. The objective of such tests, when carried out routinely, allows prompt corrective action to maintain x-ray image quality. It is important to note that the ultimate responsibility for quality control rests with the physician in charge of the x-ray facility, not with the regulatory agency.

Radiology Department QA Committee

In a hospital x-ray facility, the radiology department should establish a formal Quality Assurance Committee (QAC). It will provide the structure required to plan and evaluate the program and to resolve quality assurance issues and problems. A QAC will also provide management with recommendations for direction to those charged with the various aspects of the program.

The QAC should have an overall documented strategy with clearly defined work plans to achieve the goals and objectives of the radiology department. The committee should include representatives from all levels of the radiology staff, meet at regular intervals and report directly to the department's management. It should recommend program policies to management and outline program specifics such as the duties and responsibilities of the staff. In addition, it should formulate the standards for image quality and regularly review the effectiveness of the program. A formal QAC will promote the importance of and encourage participation in the department's QA program.

Radiology Department QA Program

A documented QA program should be developed, under the guidance of the QAC, specifically to address the needs of the radiology department. The QA program should include a written plan of action outlining policies and procedures. It should clearly define the goals and objectives of the department.

The QA program should cover both QC testing techniques and administrative procedures. The latter are to verify that QC testing is effective, i.e., the tests are performed regularly and correctly, the results evaluated promptly and accurately, and the necessary action taken. They include recommendations regarding the responsibility for quality assurance action, staff training, equipment standards, and the selection of the appropriate equipment for each examination. The quality assurance program should include the means to evaluate the effectiveness of the program

itself, e.g., ongoing retake rate and causes, equipment repair and replacement costs and analysis of trends in the equipment performance.

A QA manual should be developed in a format that allows easy reference by staff and permits future revision by management and the QAC. The content of the manual should be determined by management with the advice of the department's QAC but it should contain the following items considered essential:

- a list of the radiology department QAC personnel and an outline of their duties, authority and responsibilities;
- a list of personnel involved in QC testing and an outline of their responsibilities;
- guidelines for equipment specification writing;
- a list of the equipment parameters to be measured and the frequency of monitoring for each x-ray system and system component;
- a description of the performance standards, with specific tolerance limits established for each QC test;
- a description of the method used to measure each parameter;
- sample (blank) forms, worksheets, charts and records used for QC testing;
- guidelines for equipment acceptance testing;
- a schedule of QC testing for each equipment (monitoring frequency);
- guidelines for photographic QC;
- guidelines for recording equipment performance;

- procedures to be followed when equipment failure occurs or when test results fall outside the tolerance limits;
- guidelines for the reject-repeat analysis program;
- a list of the publications where detailed instructions for monitoring and maintenance procedures for each equipment can be found (although separate from the QA manual, service and technical operations manuals should be readily available);
- guidelines for equipment appraisal and replacement;

- guidelines for the standardization of patient exposure, e.g., patient positioning, loading factors and measurement of patient exposure;
- guidelines for quality acceptance of diagnostic radiograms; and
- a schedule of management's review QC reports and the QA program.

QA Personnel Training

The QA program should include the means to provide appropriate training for all personnel with QA responsibilities and especially those directly involved with QC testing. A continuing education program is necessary to keep personnel up-to-date. Since QC training is expensive, yet proven to be cost effective, effort will be required by hospital management to ensure that adequate financial provision be available to meet this requirement.

QC Technologist

All staff in the radiology department should be involved in quality control. However, specific tests are usually performed more effectively by specially trained technologists. The amount of time spent on QC should be adequate to perform the functions required for an effective quality control program. QC technologists should be allowed to devote at least 50 per cent of their time to a QC program in small institutions (200 beds or less) and full time in larger institutions. Institutions with more than 500 beds may require additional help. Among the activities of the QC technologist(s) should be to:

- carry out the day-to-day QC tests on the department's photographic, radiographic and fluoroscopic imaging equipment as prescribed by the QC test schedule;
- record and/or chart the QC test measurement data;
- evaluate the test results;
- report any deterioration or trends in equipment performance to the radiology manager and staff using the equipment;
- initiate prompt corrective action and/or preventive measures when necessary;

- oversee the repair of defective equipment performed by the hospital biomedical or electronic maintenance staff or by private service companies;
- perform the required tests to confirm that defective equipment was repaired and restored to the original level of performance;
- maintain equipment performance records;
- provide monthly reports on QC activities to the radiology manager; and
- develop new QC monitoring and maintenance procedures as required.

The person in the position should report directly to the radiology manager.

Equipment Specification Writing

The QAC should assist in determining the technical specifications of new equipment being purchased, based on the facility's clinical imaging requirements. The department's QA program should provide guidelines for writing equipment specifications to assist management or the procurement committee during the equipment selection phase. The guidelines should cover the general requirements specified for equipment selection with a view to upgrade or maintain the department's standard for diagnostic imaging quality. The content of the guidelines for writing specifications for each type of diagnostic equipment system or system components intended for purchase should be determined by management, with participation from the QAC, but the following elements are considered essential:

- the desired level of quality of equipment, i.e., the system design, construction and performance that can reasonably be achieved and maintained;
- the conformance standards applicable to the equipment specifications and the facility, e.g., international, federal, provincial, local regulatory requirements and occupational health and safety codes;
- the standard of equipment performance and the tolerance limits set for each equipment parameter;

- the specific equipment acceptance testing protocol and conformance standard to be followed during the acceptance phase of the equipment purchase, i.e., the specified equipment performance criteria, specification of the testing equipment, the test methods and schedules, the delegated person(s) with authority to perform the tests and authorize the acceptance;
- the removal, reinstallation and upgrading or disposal of existing equipment;
- the delivery and installation of equipment purchased, e.g., delivery date and delivery coordinator, associated responsibilities and liabilities during transit;
- the level of equipment guarantees and warranties, i.e., the extent and duration of warranty, cost of equipment or component replacement and servicing schedule requirements;
- the extent and cost of service contracts with the equipment supplier, i.e., minimum response time, availability of parts and components, qualifications and availability of service personnel and cost of service calls;
- the cost of the system, system components and ancillary equipment, the cost of delivery and installation; and
- the test equipment necessary to measure the system parameters, i.e., exposure meters, irradiation time measuring devices, x-ray volt meters, focal spot test tools, aluminium attenuators, image resolution test tools and patient equivalent phantoms.

The purchase specifications should include all of the important parameters to be monitored throughout the useful life of the equipment. These should be retained for use during the acceptance testing phase.

QC Test Equipment

The adequacy of the department's QC test equipment and radiation measuring instrumentation should be reviewed periodically by the QAC. Specifications for new test equipment intended for purchase should include the following items:

- the equipment specifications (accuracy, precision, sensitivity, range, etc.);

- a calibration reference;
- compatibility with existing equipment;
- the expected useful life of the equipment;
- the availability of parts and service;
- an estimate of maintenance costs; and
- instructions and/or training in the operation of the equipment.

Specific instrumentation required to achieve an effective level of equipment QC monitoring should be determined by management with participation from the QAC, but the following basic items are considered essential:

- Processor QC monitoring equipment: sensitometer, densitometer, thermometer, stop watch or a watch with sweep second hand, and graduated transparent beaker.
- Radiographic and/or fluoroscopic x-ray QC monitoring equipment: exposure/exposure rate meter with a full range of ionisation chambers, electronic x-ray timer, electronic kVp meter, aluminium attenuators for HVL measurements, collimation accuracy test tools, high and low contrast resolution test tools, and patient equivalent phantoms.

Other QC test instruments that should be considered, depending on the complexity and type of diagnostic imaging equipment, are listed in Part II (worksheets) of this article.

Equipment Acceptance Testing

The purpose of post-installation acceptance tests is to insure that the x-ray equipment operates correctly and meets the following criteria:

- the standards of design, construction and functioning, for diagnostic x-ray equipment as specified in the Radiation Emitting Devices Regulations, Part XII⁶ and applicable provincial regulations;
- the purchase contract specifications; and/or
- the original equipment manufacturer specifications.

Acceptance tests should be performed on every diagnostic imaging system or major equipment system component purchased prior to routine service. The QAC should be directly involved in the equipment acceptance testing phase to ensure that the equipment meets the specifications indicated in the purchase agreement.

The QA program should provide documented guidelines to assist the QAC in developing the appropriate acceptance testing protocol for all major diagnostic imaging equipment purchases. The protocol should be incorporated into every purchase specification. The content of the guidelines should be determined by management with participation from the QAC, but the following elements are considered essential:

- a list of the equipment specifications and tolerances;
- the conformance standards and the tolerance limits for each parameter to be tested;
- a list of the equipment required to test each parameter;
- a detailed method (protocol) of testing for each parameter;
- a schedule for the completion of each test;
- a list of the persons authorized to perform or witness the acceptance tests; and
- a list of the persons responsible for authorizing the acceptance of each test.

The report on the acceptance tests results should contain all of the information listed above including the actual data with graphs, charts and test films for each equipment parameter tested. This report should be retained as part of the equipment performance log book and used to compare with future QC test results to assess the continued acceptability of the equipment's performance and estimate the equipment's remaining useful life.

QC Testing Program

The purpose of a QC testing program is to maintain the quality of diagnostic images. This is done with routine monitoring of photographic and x-ray equipment parameters to detect deviations of

equipment performance and take prompt corrective action. Periodic monitoring should not be eliminated if the test results indicate relatively stable equipment performance. Small but progressive changes in image quality, not readily detectable to the eye, will be more easily noticed using standardized test procedures and specific test equipment. The most important objectives of a routine QC testing program are to:

- establish a baseline against which future measurements can be compared to maintain the original level of performance;
- assist in detecting and diagnosing the cause of any deterioration in equipment performance;
- promptly correct any deterioration in equipment performance when the cause is known;
- detect defects on installation, or after major repairs, which may adversely affect image quality or patient dose; and
- enable comparable loading factors to be used on similar x-ray machines, where appropriate.

The QC testing program should be divided into component parts to cover each area effectively.

For example:

- general radiography, i.e., photographic, radiographic and fluoroscopic equipment QC;
- mammography, i.e., photographic and radiographic equipment QC; and
- computed tomography, i.e., image quality and radiographic equipment QC.

X-Ray Equipment QC

It is advisable to determine and document the many important aspects of the monitoring and maintenance activities in the QC manual. The manual should provide the following information:

- a list of all x-ray and ancillary diagnostic imaging equipment systems located in each x-ray room or operating room under the control of the radiology department;
- a list of the parameters monitored for each equipment;
- the priority given to each parameter measured, i.e., "desirable" or "essential" based on equipment type, types of examinations and experience;
- the frequency of testing required for each parameter, i.e., daily, weekly, monthly, etc.;

- the acceptable range within which the equipment must function;
- the tolerance levels outside which the equipment should not continue in use;
- detailed QC monitoring protocols (test sheets) clearly describing the title of the test, the purpose of the test, the frequency of testing, the test equipment required, the test procedure to follow, and the tolerance limits for each test of each part or type of equipment; and
- a list of the most suitable person(s) to carry out each routine start-up procedure, routine QC tests, preventive maintenance procedures, corrective action or repairs. For example, only qualified x-ray service personnel should repair equipment.

Photographic Equipment QC

Undoubtedly the most important item in diagnostic imaging quality control is routine (daily⁷) photographic processor control. Contaminated film processing solutions or small changes in developer temperature affect both the image quality and the patient exposure. For routine processor control to be effective, the sensitometric data must be evaluated promptly and the necessary corrective actions taken before x-rays are taken of patients. This is to ensure that the x-rays will be processed correctly and to minimize retakes. Often, the early morning's processor control test data are evaluated later in the day and the necessary corrective actions are taken too late to be effective. Unless the processor is monitored closely to ensure optimum performance then all other efforts at QC will probably be in vain. Along with processor sensitometry there are many other tests that should be done to ensure proper operation of the film processing unit. These tests are listed in "Radiographic Quality Control, Minimum Standards"⁷ and Table A.1 in NCRP Report No. 99.⁸

The radiology department should adopt an effective silver recovery and chemical effluent control program. Silver recovery can be split into two parts, that from the fixer and that from old or discarded radiograms. Most institutions recognize that the silver in the film is recoverable and may represent as much as 10 per cent of the purchase price of good "green" film, depending on the current silver and film prices. New silver recovery systems currently available will recycle the

fixer and developer and minimize the negative effects on the environment by removing silver salts and other toxic substances from the effluent.

The effectiveness of the QC monitoring program should be reviewed annually by the QAC. Guidelines such as "Radiographic Quality Control, Minimum Standards"⁷ or Appendix A: "Summary of Quality Control Tests"⁸ or "Diagnostic X-ray Equipment and Facility Survey"⁹ should be reviewed to determine a list of "essential" and "desirable" QC tests to be performed routinely.

Equipment Performance Records and Record Keeping

The method of record keeping should be determined by management with advice from the QAC. The records may be maintained in a file or individual log books or in a computerized data base. Commercial software is available and can be customized with relative ease to record the data collected. In some cases the measured kilovoltage, exposure time and exposure is transmitted directly from the radiation detection meter to the computer.

The records should be maintained in a ready-to-use form and the information be readily available to all staff. The information should be complete, up-to-date and presented in a form suitable for departmental reviews and provincial radiation safety audits.

The equipment performance record should clearly identify the equipment and its location. It is recommended to keep one log book for each x-ray room. The required equipment performance data should be determined by the QAC but the following elements are considered essential:

- the equipment system identification, i.e., the name of manufacturer, the model designation and serial number, the date and country of manufacture;
- the equipment location;
- a copy of the equipment acceptance test report;
- a copy of the current provincial radiation safety survey;

- a copy the current federal, provincial or territorial registration certificate;
- the QC monitoring records (data, graphs, charts, etc.);
- the equipment service and repair record including service frequency and costs; and
- the equipment down-time record.

Equipment Appraisal and Replacement Policy

The radiology department's financial policy should include provision for the replacement of x-ray equipment. Although x-ray equipment normally has a life expectancy of 10 to 15 years, replacement costs often require a large share of the capital available. Even within this relatively long period there should be plans for the replacement of major components that deteriorate rapidly with use and age, such as image intensifiers, x-ray tubes and ancillary equipment like intensifying screens.

The department's QA program should provide documented equipment appraisal and replacement policy guidelines to assist management in the financial planning related to the replacement of aging equipment. The guidelines should be based on an estimate of the equipment's remaining useful life determined by the following long-term equipment performance items:

- decreasing image quality, increasing exposure to patient and staff, and decreasing patient flow;
and
- increasing operating costs, increasing number of service calls, and increasing equipment down time.

Standardization of Exposure

The following three sections relate to patient exposure: radiographic positioning, loading factors and entrance-skin-exposure. The recommendations listed in each section are given with a view to maximize the diagnostic quality of radiograms and minimize patient exposure.

Radiographic Positioning

The radiographic positioning manuals should be reviewed regularly by the QC technologist and the information updated and maintained in clear typewritten form. The radiologists should determine which views are required for each examination, e.g., lumbar spine: AP, LAT, L5-S1, etc. The contents of the radiographic positioning manuals should be determined by management with participation from the QAC, but the following information should be included:

- the body part to be examined;
- the projection to be shown;
- the number of projections required;
- the part rotation;
- the image receptor size used for each view;
- the source-to-image receptor distance;
- the tube angle;
- the trajectory of the central ray;
- the details of structures to be shown; and
- detailed instructions to correctly position the patient, the x-ray tube and the image receptor to obtain satisfactory and consistent results. Illustrations are recommended.

Loading Factors

The loading factors manual should be reviewed regularly (e.g., monthly) by the QC technologist and each chart updated and maintained in clear printed form. Changes should not be maintained in hand-written form. The contents of the loading factors manual should be determined by management with participation from the QAC but the following information should be included:

- the body part and projection;
- the patient size or body part thickness;
- the optimum kVp;

- the optimum mA and time, or mAs, or AEC including the specific cell;
- the film/screen combination selection;
- the grid selection; and
- the tube focal spot size selection.

Any change made to loading factors, to compensate for decreased diagnostic image quality, should be investigated to determine the cause. Poor film processing is the most frequent cause of a decrease in image quality.

The method used to derive loading factors, i.e., fixed kVp or fixed mAs, should be determined by the radiologist. Loading factors derived from the subjective evaluation of patient size are unreliable and do not provide consistent radiographic images. All patients should be measured and the loading factors adjusted accordingly. For example, to compensate for variations in patient sizes, using fixed mAs techniques, the method of increasing or decreasing the kilovoltage by approximately 2 kVp per centimetre of body part can be employed.

Commercial software is available to generate loading factor charts for the examples listed above in both DOS and Windows. The loading factor charts can easily be updated on the computer and printouts made.

Where phototiming (automatic exposure control) is used, the specific photocell(s) to be utilized should be specified and the density setting defined for each range of patient sizes. Each range of patient sizes (small, medium or large), for both adults and children, should be defined and the selection derived from actual physical measurements of the patient.

Entrance-Skin-Exposure

The entrance-skin-exposure (ESE) should be measured and recorded for standard radiographic examinations or projections. The standard projections recommended for routine QC ESE

measurement should be based on those found in Tables 1 and 2 of Safety Code-20A¹⁰ and are listed in Table 1.

Table 1. Recommended Upper Limits for Entrance Skin Exposure

Examination (Projection)	Entrance Skin Exposure	
	Recommended Upper Limits	
	(mR)	($\mu\text{C/kg}$)
Chest (P/A)	20	5.2
Skull (Lateral)	224	58.0
Abdomen (A/P)	627	162.0
Cervical Spine (A/P)	137	35.0
Thoracic Spine (A/P)	380	98.0
Full Spine (A/P)	263	68.0
Lumbo-Sacral Spine (A/P)	614	158.0
Retrograde Pyelogram (A/P)	539	139.0

The recommended upper limits for ESE given in the table above are based on:

- the third quartile levels from unpublished (Canadian) Nationwide Evaluation of X-Ray Trends (NEXT) data; and
- a reference patient having the anthropometrical characteristics shown in Table 2.

Table 2. Anthropometrical Characteristics of the Reference Patient

Body Part	Reference Patient Thickness
	(cm)
Head (lateral)	15
Neck (A/P)	13
Chest (A/P)	23
Abdomen (A/P)	23

Note: In practice, it should be feasible to have actual ESE substantially lower than these limits.

This series of ESE measurements should be performed at least semi-annually for every radiographic equipment system or each time the radiographic system is repaired or serviced. The ESE measurement results should be used to update the information contained in the radiographic

technique chart.

Commercial software is available and may be used to calculate the ESE. After the basic information is entered into the computer program, the computer is able to calculate the ESE for any given examination or loading factors or patient size.

The measurement of standard fluoroscopic exposure rates for the average-sized patient should be performed regularly for all fluoroscopic equipment systems. The frequency of measurement should be monthly and always after service or repair of the fluoroscopic system. The measurements should include all exposure rate delivery modes where applicable and measured in both the manual and automatic exposure rate control mode operation. The radiologist should be informed regularly about the results.

The maximum exposure rate should be measured at least every six months⁷ for every fluoroscopic equipment system. Measurement should include both the manual and the automatic brightness control mode operation.

The loading factors used during fluoroscopic procedures (time, kilovoltage and tube current) should be recorded on the patient requisition form or the patient's chart.

Acceptance Criteria for Diagnostic Radiograms

Guidelines should be developed to determine the minimum level of diagnostic quality acceptable to the radiologist. Comprehensive acceptance criteria should be established for all radiographic views. The department's radiologist should be directly involved in developing these guidelines. The following additional diagnostic quality acceptance criteria are recommended for consideration:

- the visibility of predetermined landmarks clearly defined for each radiographic view;
- the acceptable film density range measured at predetermined anatomical landmarks; and

- three limits of acceptability that clearly define whether the x-ray technologist forwards the radiogram to the radiologist for reporting, or the x-ray technologist consults with the radiologist, or the radiogram is rejected and a repeat is done.

These acceptance criteria should be further refined, in an effort to closely approximate the radiologist's subjective impressions of image quality. They should be very useful to "pre-screen" radiograms of questionable diagnostic quality before being viewed by the radiologist. This information is necessary, e.g., when new staff are introduced to the department, when staff are working alone on weekends or evenings, etc., and will provide guidelines to follow when the radiologist is not available.

Reject-Repeat Analysis Program

Guidelines for an effective reject-repeat analysis program (RRAP) should be documented and included into the department's QC protocol manual. Such guidelines are described in "Quality Control in Diagnostic Imaging Equipment."¹¹ Staff must be made aware that the object of a reject-repeat analysis program is not to embarrass anyone, but to identify problem areas and train or retrain those who are unable to perform certain radiographic examinations. In turn this will reduce the number of rejected radiograms and reduce patient and occupational dose. The RRAP guidelines should also include documented standards to aid in the analysis and classification of rejected radiograms. Such guidelines are necessary for consistent classification and comparison of data.

The basic RRAP should be refined to determine how many rejected radiograms or repeats were acceptable and did not need repeating and the reasons for this determination. The radiologist should be involved in this aspect of the program. A thorough analysis may find that some rejected radiograms were repeated unnecessarily. The information derived from the reject analysis program can be of benefit and should be communicated to all x-ray staff, for example during in-service training workshops.

QA Program Review

The diagnostic imaging QA program should be reviewed regularly by the department's QAC to determine the effects of each quality assurance action. Among the items recommended for review are:

- the reports on monitoring and maintenance techniques should be reviewed at least quarterly to ensure that these are being performed effectively;
- The monitoring and maintenance techniques and their schedules should be updated at least annually to ensure that they continue to be appropriate and in step with the latest developments in QA;
- the standards for image quality should be reviewed at least annually to ensure that they are consistent with the state of the art and the needs and resources of the facility;
- the effectiveness of QA procedures should be reviewed at least annually to determine where improvements are required; and
- the approach and effectiveness of the QA program compared to that of outside groups (scientific and/or professional societies, national authorities, etc.), to identify areas where improvements can be made.

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