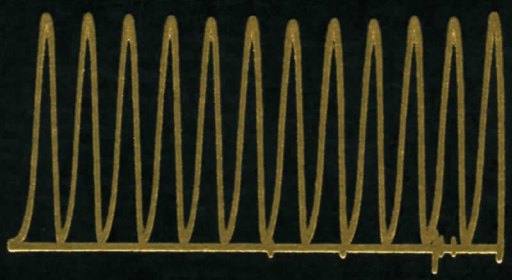
QUALITY CONTROL IN DIAGNOSTIC IMAGING



Joel E. Gray,
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John Stears, and
Eugene D. Frank

AN ASPEN PUBLICATION

Quality Control In Diagnostic Imaging— *A Quality Control Cookbook*

This book was first published in 1983 and is now being provided in Adobe Portable Document Format (PDF) for use in clinical diagnostic medical physics residency training programs.

Diagnostic imaging technology has changed significantly in over 25 years. For example, video tape and disk recorders have been replaced with digital recording systems. Although the technology has changed the types of tests required today are similar to those described in this book.

Many other sources of quality control test procedures are now available through the American College of Radiology (Reston, Virginia) at:

http://www.acr.org/SecondaryMainMenuCategories/quality_safety.aspx

http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/tech-standards-mp.aspx

http://www.acr.org/SecondaryMainMenuCategories/quality_safety/RadSafety.aspx (includes ACR Quality Control Manuals)

the American Association of Physicists in Medicine (College Park, Maryland) at:

http://aapm.org/pubs/reports/

the National Council on Radiation Protection and Measurement (Bethesda, Maryland)

http://www.ncrppublications.org/Reports/

http://www.ncrppublications.org/Commentaries/

and the International Atomic Energy Agency (Vienna, Austria) at:

http://www-pub.iaea.org/MTCD/publications/publications.asp

Consequently, this quality control book has not been revised and republished.

This PDF version of this book was created by scanning a paper copy of the original book. Consequently, some limitations have been encountered. For example, some figures contain a slight moiré pattern due to the interference between the lithographic screens used to reproduce

the photographs in the original document and the scanner-digitization process. For these we apologize. However, the intended information is reproduced with reasonable fidelity.

Since this is a scanned version of the original book, the PDF files are not searchable.

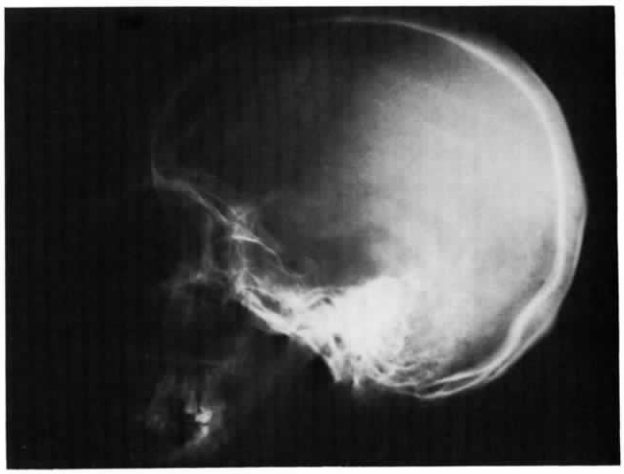
Finally, blank pages, i.e., at the end of chapters, have not been included.

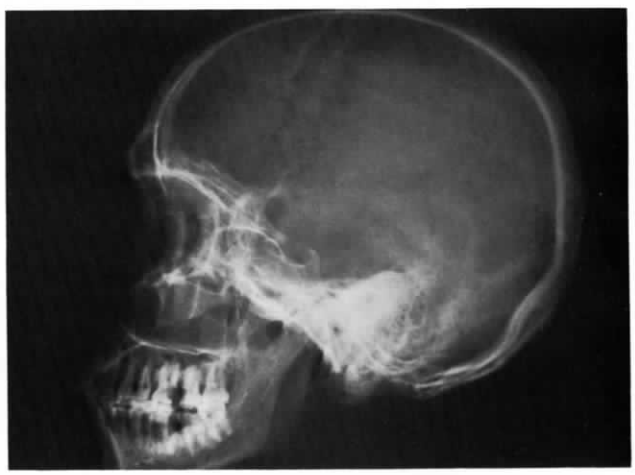
Hopefully this PDF version will be a valuable resource to those entering the field of clinical diagnostic medical physics.

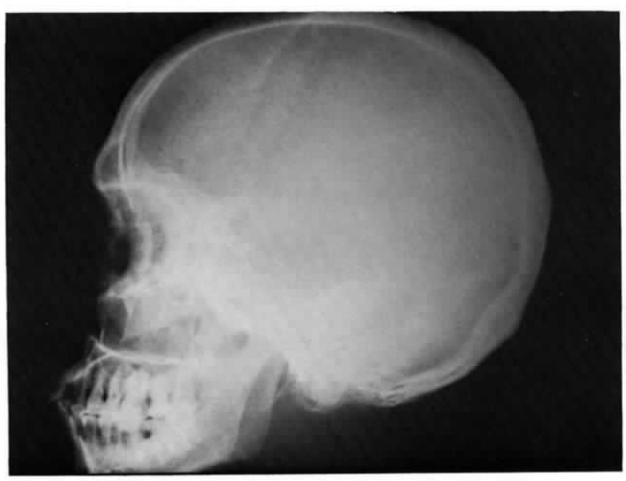
QUALITY CONTROL IN DIAGNOSTIC IMAGING

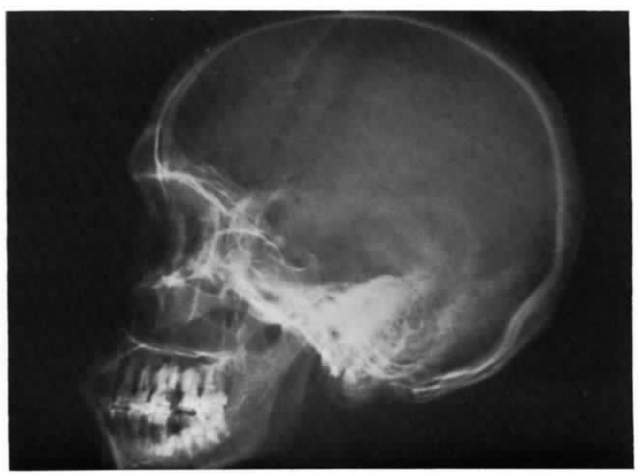
Poor quality (before quality control)

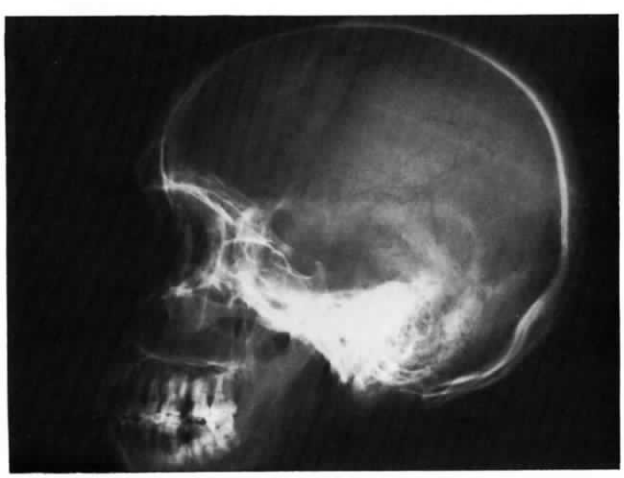
Excellent quality (after quality control)

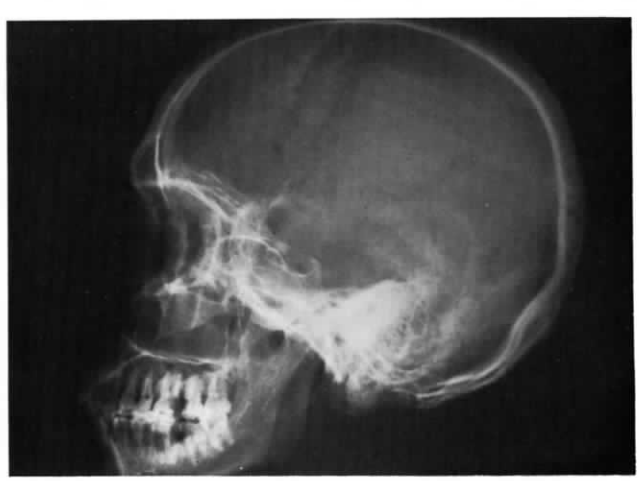












QUALITY CONTROL IN DIAGNOSTIC IMAGING

A Quality Control Cookbook

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AN ASPEN PUBLICATION®
Aspen Publishers, Inc.
Gaithersburg, Maryland
1983

Published by:
Aspen Publishers, Inc.
200 Orchard Ridge Drive
Gaithersburg, Maryland 20878

Library of Congress Cataloging in Publication Data
Main entry under title:

Quality control in diagnostic imaging.

Includes bibliographical references and index.
1. Radiography, Medical—Quality control.
2. Imaging systems in medicine. I. Gray, Joel E.
RC78.Q34 1982 681.41 82-13446
ISBN: 0-8391-1681-0

Manufactured in the United States of America

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CONTENTS

PREFACE

This book is designed to be used by everyone in diagnostic imaging, each at his or her own level:

For the *radiologist*—We provide basic discussions on what is required for quality assurance and control in diagnostic imaging. We provide information on the type of equipment necessary for quality control (QC), and the training necessary for the QC technologist, as well as an overview of the tests (detailed test instructions are provided separately in the procedures section of each chapter).

For the *physicist*—We provide information concerning the initiation and maintenance of a quality control program. Specific detailed procedures for carrying out tests, including measurement techniques and problems, will help the physicist better guide the direction of the QC program in institutions of various sizes. This book will also provide a basis for other, more specific tests that the physicist may find it necessary to develop.

For the *radiology resident*—We provide a readable introduction to the problems associated with x-ray equipment. The information contained in this book will be of use to the resident entering practice since it will provide insight concerning x-ray equipment he or she will be using and purchasing in the future. This book will also be useful in a residency training program since physics can be taught with a purpose: the quality control and understanding of equipment. The procedures sections of the book can easily be used for laboratory experiences as part of the radiology residency physics program.

For the *radiology administrator*—We provide an introduction to quality control programs, with an overview sufficient for an understanding of the problems associated with administering such a program. The details of the tests, which are not of interest to most administrators, are provided separately in the procedures section of each chapter.

For the *service engineer*—We provide a complete set of noninvasive tests. Although these may not measure exactly what the engineer invasively measures, they can be used to monitor the output of x-ray equipment. These measurements, in conjunction with invasive testing, can be very beneficial in situations such as determining the possible loss of x-ray tube emission. This book will provide the engineer with sufficient insight to better troubleshoot problems reported by quality control technologists who are using these tests on a regular basis. The full complement of image quality tests, including fluoroscopic tests, will be useful to the service engineer. In addition, the tests in this book may be carried out by the less experienced engineer in a training program, providing valuable information as well as experience.

For the *technologist*—Last, but by no means least, we mention the technologist, the person for whom this book is primarily designed since it is this group of professionals who will make the most use of the book and the test procedures that we describe. The staff technologist will benefit from the clearly described test protocols and acceptance limits, as well as the control charts and logs provided. The student technologist will find this book readable and usable. In a student technology program this book can be used as the basic text for a quality control course in conjunction with a physics and imaging text. In fact, physics and imaging can be taught from a new perspective—quality control being taught to make physics and imaging, and the equipment,

understandable. This is the opposite approach of many courses, which teach physics and imaging on a theoretical basis and leave it to the student to apply the principles. Now, with this book, the physics and imaging principles can be taught, as needed, to support the practical and necessary work in quality control—at last, a reason for the technologist to study physics!

This book is based upon extensive experience in quality control at our institution. The test procedures have been thoroughly tested in evaluating many rooms of x-ray equipment. The acceptance limits we present have been developed on the basis of our experience, in terms of what we have found is reasonably possible to expect of the equipment and what we have found to be necessary to provide consistent, high-quality radiographic images for diagnostic purposes. The book is based on experience in large and small departments, since our institution supports a cross-section of diagnostic imaging facilities (over 200 x-ray tubes in a large outpatient facility and two hospitals; a small community medicine facility; several outreach facilities ranging in size from a one-x-ray unit facility to a small community hospital).

The contents of this book are unique in that discussions of theory have been eliminated in preference to discussions of practical problems and pitfalls. Material not directly applicable, such as discussions of the components of photographic developer or the difference between Y and delta configuration transformers, is not included in order to make this a succinct, more readable, directly applicable book. Extensive use is made of illustrations and figures both to show the test setup and to demonstrate acceptable and unacceptable results of the tests.

The first chapter ("Introduction") provides an overview of quality control programs. Chapter 2 ("Equipment and Measurement Tips") is a primer on basic quality control equipment and measurement tips for the quality control technologist. (We have studiously avoided the mention of manufacturers' names throughout the book so as not to slight anyone. Most equipment is available from several manufacturers and vendors.)

The use of control charts, the key to a good quality control program, is the subject of Chapter 3 ("Basics of Quality Control"). The establishment of operating levels and control limits as well as room logs is also covered. Chapter 3 should be considered the basis for the quality control program since without adequate records and an easy way to review the data a quality control program will become a data collection program, with no obvious benefit.

Starting with Chapter 3, each chapter is broken into two sections. First there is a general discussion of the tests and then a detailed procedures section provides a protocol, or cookbook, approach to carrying out the tests and analyzing the data. For each of the procedures we have also included a section called "Problems and Pitfalls," an understanding of which is essential to obtaining reliable data.

Reject-repeat analysis is discussed in Chapter 4, but excessive emphasis is not placed on this aspect of quality control. As we mention, the reject or repeat rate can be reduced to close to zero if the radiologist is willing to read every film that comes out of the processor.

Chapter 5 is devoted to photographic quality control since this is usually one of the major problem areas in diagnostic imaging. Hundreds of thousands of dollars worth of imaging equipment will only produce images as good as that which is produced by the final link in that chain, the processor. The processor can be, and often is, the weakest link in the imaging chain, requiring daily monitoring and constant attention. Also described is a flood replenishment system, which may be the only way to obtain consistent photographic processing quality if fewer than 50 sheets of 14 × 17-inch (35 × 43-cm) film are processed in any processor each day, or in an application where the processor handles an abnormally high percentage of single emulsion films.

Chapters 3 ("Basics of Quality Control"), 5 ("Photographic Quality Control"), and 6 ("Basic Tests") should be considered the backbone and starting point of a quality control program. The basic tests are designed to be carried out with a minimum of test equipment—these tests can be carried out while the department is awaiting the arrival of quality control test tools! However, the fact that these tests are basic does not imply that they should not be part of a more sophisticated QC program. Each one of the basic tests, or a more sophisticated version of each, is an integral part of an ongoing quality control program.

In Chapter 7 ("X-Ray Tubes and Collimators") a significant amount of time is spent discussing rating charts and overload protection, since it has been our experience that the lack of understanding of rating charts probably leads to the majority of x-ray tube failures—tubes that cost from $6,000 to $20,000 each. The purpose of this discussion is to better acquaint the QC technologist with these charts so that he or she can develop technique charts that will allow the

optimum usage of the equipment while avoiding tube problems.

Chapters 8 through 11 provide a discussion of the radiographic, fluoroscopic, conventional tomographic, and portable equipment to be evaluated, as well as detailed test procedures. The last chapter ("Equipment Specification, Purchase, and Acceptance Testing") provides some guidelines for specifying and acceptance testing equipment, as well as some comments concerning our experience in working with the vendors.

Quality control forms, control charts, technique charts, maintenance request forms, and equipment specification forms are provided in the appendices. These may be reproduced for use in your institution, but may not be reproduced for sale without permission of the authors and publisher.

This book describes the basis for the quality control program at our institution, of which we are, naturally, quite proud. We feel that we produce some of the best diagnostic films in the world while maintaining the exposure to our patients and staff at a minimum level. In addition, since our retake rates have been minimized through the use of quality assurance (including QC, staff training, and in-house service) we have minimized the cost of operating our department. In other words, we feel we are doing our best in the three areas of importance in diagnostic imaging—

Diagnosis—best diagnostic image quality
Dose—minimized exposure to patients and staff
Dollars—reducing the cost of health care

We hope this book and your quality control program will benefit your department as they have benefitted ours.

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1 INTRODUCTION

Quality assurance and quality control are rapidly becoming familiar words in diagnostic imaging. The federal government has published recommendations for quality assurance programs in diagnostic imaging facilities (Bureau of Radiological Health, 1980). The Joint Commission on the Accreditation of Hospitals (JCAH) states that one of the responsibilities of the director of radiology services is the "maintenance of a quality control program to minimize the unnecessary duplication of radiographic studies and to maximize the quality of diagnostic information available" (Joint Commission on the Accreditation of Hospitals, 1980). In addition, most of the professional societies are endorsing quality control and are publishing guidelines for quality assurance and quality control programs.

Before continuing, let's examine the differences between quality control and quality assurance. First of all, quality assurance is defined as:

> A system of activities whose purpose is to provide assurance that the overall quality control job is in fact being done effectively. The system involves a continuing evaluation of the adequacy and effectiveness of the overall quality control program with a view to having corrective measures initiated where necessary (Thomas, 1973).

Quality assurance includes many facets of activities such as quality control, preventive maintenance, equipment calibration, in-service education of the technologists and darkroom personnel, specification and acceptance testing of new equipment, and evaluation of new products.

Quality control is defined as:

> The overall system of activities whose purpose is to provide a quality of product or service that meets the needs of the users; also, the use of such a system. The aim of quality control is to provide quality that is satisfactory, adequate, dependable and economic (Thomas, 1973).

In other words, the quality assurance program is the overall management program, whereas the quality control program is that segment of the quality assurance program that is responsible for the measurement of the image quality and the integrity of the equipment.

It is interesting to note that these definitions are provided in a publication issued by a photographic science and engineering society. Quality assurance and quality control have been integral parts of the photographic industry and many other industries for decades for both the manufacturer and the user (e.g., the motion picture industry and the field of aerial reconnaissance and mapping). Up until the early 1970s most radiology departments were not familiar with the concept of quality control, to say nothing of having active quality control programs.

We concern ourselves primarily with quality control (QC) throughout this book, although some of the aspects of quality assurance (QA) are discussed briefly. We look at the justifications for QC, discuss the number of people needed for an effective program, and most importantly, provide a step-by-step approach for QC, along with suggestions concerning the extent and frequency of tests for various types of equipment.

WHY QUALITY ASSURANCE?

Quality assurance is becoming similar to motherhood, apple pie, and the American flag—everyone must believe in it, enjoy it, and respect it. But why are we really interested in quality assurance? The real justification for QA and QC efforts rests with the results we hope to obtain, which we refer to as the three Ds:

*D*ose
*D*iagnosis
*D*ollars

First of all, we hope to minimize the "Dose" to the patient so that as much as possible the potential benefit of the examination outweighs the risk. (While we are reducing the dose to the patient, we are also reducing the exposure to the staff.) If we accomplish the reduction in dose while maintaining and improving the quality of the image or diagnostic information, then we can be sure we are optimizing the "Diagnosis" or, more specifically, the diagnostic information upon which the diagnosis will be based. Last, and perhaps least, if we reduce the number of retakes, we will be improving the utilization of our resources and reducing the amount of film and chemicals we consume, and ultimately reducing the cost of the examination and saving "Dollars."

We place the cost savings lowest in our priorities since it is difficult, at best, to justify the cost of a quality assurance program on the basis of financial savings alone. One could always argue that the best way to reduce the number of retakes and the cost of supplies is to have the radiologists accept and read every film that comes out of the processor.

In many institutions, it is difficult to identify actual cost savings because of the many other variables one must take into consideration in carrying out such a study. However, there are several studies available in the literature indicating savings that at least cover the cost of the quality assurance program (Blackham, 1977; Goldman et al., 1977; Hall, 1977; Nelson et al., 1977; Linton et al., 1979; Fields et al., 1980; Noyes, 1980). In addition to savings in direct costs due to savings in film and chemicals, one may realize indirect savings in terms of a reduced workload for the technologist. This in turn may lead to increased patient flow and better utilization of the equipment and facilities.

In terms of direct costs, Nelson et al. (1977) found that their annual savings in film and chemicals alone was about $27,000 after the initiation of a quality control program. Blackham (1977) noted a 20% decrease in film costs after initiating a QC program even though there was a 3% increase in the number of studies carried out. Hall (1977) found that an institution spending $150,000 annually for film and chemicals could save $10,000 with a QC program. Goldman et al. (1977) estimated savings for just a photographic QC program would amount to $6300 per year for a facility producing 100,000 radiographs. Noyes (1980) estimated annual savings ranging from $33,000 to $51,000 for a department with 12 examining rooms.

Another area of potential savings is in the reduction of downtime of the equipment. However, it has been our experience that this is even more difficult to quantitate than the cost savings since breakdowns still occur (usually in the middle of a very busy morning with many patients waiting) and it is difficult to identify impending equipment failures before they occur. In fact, failures can occur immediately after QC checks have been carried out, thereby casting doubt on the efficacy of quality control in the mind of the more cynical administrator. Also, it must be remembered that QC checks require the use of the x-ray equipment and may reduce the patient flow. If you are concerned about downtime, the best answer to this problem is to establish, if feasible, an in-house service program to go along with the quality control program.

QUALITY CONTROL AND THE PROFESSION

Even though there are real savings with quality control programs in terms of the cost of expendables and potential savings through the better utilization of facilities, an even more important reason to initiate and maintain a QC program is related to the professionalism and pride the technologist should take in doing the best job possible. You, as a technologist, are an important contributor to the care of the patients at your clinic or hospital. The radiologists rely on the competency of the technologists to produce the best films possible, a trust and reliance that is rather unique in the medical field. As technologists you should do everything that you can to assure that your professional relationship with the radiologists is maintained and nurtured. A QC program will be a real asset to you, to your department, to your patients, and to your radiologists.

WHO IS RESPONSIBLE FOR QUALITY CONTROL?

The ultimate responsibility for quality control in a radiology department rests with the radiologist

responsible for that facility (Bureau of Radiological Health, 1980; Joint Commission on the Accreditation of Hospitals, 1980). However, in most instances this responsibility will be delegated to the radiologic physicist, the chief technologist, or a QC technologist. In actuality, quality control is everyone's responsibility.

You must decide how best to initiate and maintain a quality control program in your facility. For example, one approach is for each technologist to be supplied with simple test tools to evaluate the particular room of equipment that he or she uses. In other words, every technologist is responsible for assuring that his or her equipment is working properly at all times. Another approach designates one or two technologists to carry out all of the necessary checks on a part-time basis, usually in the afternoon when the work load is lighter. Still another approach assigns a technologist to carrying out the QC tasks full time, although this is usually only feasible in larger institutions. In very few facilities does the chief technologist carry out the QC checks, since the chief technologist is usually already overburdened with other responsibilities and administrative tasks.

There are distinct advantages and disadvantages to each of these approaches. If every technologist is responsible for his or her individual room, then each technologist must be trained in the use of the test tools. This usually limits the complexity of the tests that can be carried out and increases the amount of test equipment that must be available. In addition, unless the technologists are highly motivated individuals who are interested in quality control, the QC tests become secondary and most frequently are neglected after a few months.

If one or two technologists are designated on a part-time basis to carry out the QC checks, especially in the afternoons when work loads are lighter, a strong commitment must be made by the department to assure that time is made available to them to do these tests. Frequently the workload requires that these technologists be utilized to fill in for someone else and the QC tests are neglected as a result.

In both of the above approaches several technologists must be trained in QC techniques. This dilution results in everyone involved being less experienced, in addition to making the training of several individuals costly in terms of dollars and time.

It would seem that a full-time technologist with sole responsibilities for quality control would be the ideal solution, but this is only feasible in larger institutions with a strong commitment to quality control. The individual with such responsibilities may obtain specialized training in quality control. In addition, this provides another possible pathway for advancement of technologists in the department and perhaps a stepping stone to higher positions.

A QUALITY ASSURANCE COMMITTEE?

Although committees in hospital facilities are known to be the largest consumers of man-hours, a quality assurance committee may prove quite useful. The committee should consist of at least one radiologist (additional radiologists representing subspecialties should be included in larger departments), a diagnostic radiologic physicist, the chief technologist, the QC technologist(s), and a representative from the in-house x-ray service or engineering group. This group should meet regularly and should provide direction to the program, determine the frequency of checks, assure that proper documentation is maintained (i.e., that which is necessary to meet JCAH requirements), and review the effectiveness of the program.

TECHNOLOGIST, PHYSICIST, ENGINEER?

Who should do what? This will depend on the relationships between the technologist, the physicist, and the engineer and on the individual expertise of each. We believe that the technologist, with proper training, should be able to carry out all of the QC tests that we describe. The physicist should be available to assist during the period when the technologist is learning to carry out and interpret the tests, but should not be required to get involved in most of the day-to-day operations of the QC program. The physicist should then be available to the technologist on a consulting basis.

Since all of the tests that we describe are noninvasive, the technologist should be able to carry them out without the assistance of an engineer. The engineer, however, should be available on a consulting basis to discuss design functions of the components and problems found by the QC technologist, and to provide the necessary expertise in calibrating and repairing the equipment. The QC technologist and engineer should work together closely in attempting to locate the cause of problems in x-ray systems. Finally, the technologist must verify the integrity of the equipment after the service engineer has completed his work, since the technologist must assure that quality diagnostic images are produced at a minimum dose to the patient after equipment service. If the technologists and engineers coordinate their work, they will find that both of their jobs are much easier.

In summary, the physicist oversees the program, develops tests as required, and monitors the measurements of radiation levels and image quality. The QC technologist carries out the day-to-day measurements in the program and maintains the QC logs. The service engineer carries out all repairs, preventive maintenance, and calibration on the diagnostic imaging equipment.

HOW MANY PEOPLE AND HOW MUCH TIME?

The number of people needed for a quality assurance program will depend on the size of the facility. A large proportion of the QC work should be done by the staff technologists in a small facility (with 5 or fewer rooms), but they should rely on a larger facility for some of the more complex measurements requiring sophisticated testing equipment. A small facility should have the services of a consulting physicist who visits the facility at least one day a month. The small facility should have a service engineer available for emergency repair calls and should establish regular preventive maintenance checks with the engineer.

A medium-sized facility (with 5 to 15 rooms) should have a part-time QC technologist and a full-time service engineer. A facility of this size should have a consulting physicist available in the facility at least one day a week and available at all times by telephone for consultation with the QC technologists and other department personnel.

A large facility (with 15 to 20 rooms) should have a full-time QC technologist and two or more full-time service engineers. A facility of this size should have a physicist working at least half-time and available in the facility 20 hours per week on a fixed schedule. In addition, the physicist should be available for consultation by telephone at all other times.

An extra-large facility (25 to 30 or more rooms) should have at least one QC technologist for each 25 rooms of equipment and one full-time engineer for each $3 million worth of equipment (this is based on replacement cost, not purchase value, of the equipment). There should be a full-time physicist available in the facility at all times.

Remember, small facilities need quality control as much as large facilities. A small facility may want to consider "time-sharing" the services of the QC technologist, the physicist, and the engineer with other facilities, or a larger facility may wish to consider providing such services to smaller facilities on an "outreach" basis. However, some quality control must be carried out by in-house technologists, including daily processor QC checks and some basic "go/no-go" tests. Consequently, each small facility must make a minimum investment in equipment, as described in the next chapter.

The QC technologist must be allotted adequate time to carry out the required tests. He or she *must* be released from clinical duties to carry out the QC tasks at specified times. For example, the QC technologist must be released from clinical responsibilities at 12:00 noon each day, *without fail,* or must be free of clinical duties on Tuesdays, Wednesdays, and Thursdays.

The amount of time needed to carry out room checks will depend on the sophistication of the tests. To check out a general radiographic room (without fluoroscopic or tomographic capabilities) will take from 1 to 2 hours. A radiographic and fluoroscopic room will take from 2 to 4 hours, and a tomographic room will take about 1½ to 3 hours. In addition, the QC technologist must have time to carry out daily processor quality control, or to supervise a designated individual who will process and read the densities of the control strips. The QC technologist must have sufficient time to troubleshoot other problems as they occur. Normally after a quality control program is initiated and the other technologists accept the program, the QC technologist will be called upon more and more to troubleshoot problems. This may mean that the technologists who are responsible for patient care are passing some of their responsibilities off to the QC technologist, but, at the same time, this is usually a more efficient use of resources since the QC technologist has the experience and equipment to quickly isolate the problems.

In addition to actual QC tasks, the QC technologists must have sufficient time allocated to update their skills, which will mean travel to other institutions and professional meetings. The QC technologist should participate in all QA committee meetings and departmental conferences as well as assist in the preparation of equipment purchase specifications. He or she will also need time to maintain adequate records of all work (this is required by JCAH), and to consult with the physicist and engineers on equipment and QC problems.

HOW FREQUENTLY SHOULD EQUIPMENT BE CHECKED?

The major goal of a quality control program is to detect changes in the equipment and have correc-

tions made *before* these changes become significant enough to affect the quality of the radiographs produced. Consequently, the frequency of tests will depend on many variables, such as the complexity of the equipment, the age of the equipment, the criticality of the equipment usage (special procedure labs versus general radiography), and the volume of work.

One must also consider the amount of variation that is inherent in the individual equipment being monitored. For example, photographic processors are about the most variable pieces of equipment in any department and consequently should be monitored on a daily basis. Special procedure labs, especially ones doing more than two or three cases per day, receive a lot of hard use and a failure in any component is quite critical. Consequently, special procedures rooms should be checked at least monthly and preferably before every case, by imaging a patient ID device along with an image quality indicator. General radiographic rooms are much less complex than radiographic and fluoroscopic (R and F) rooms and will probably require checking about every 6 months, whereas R and F rooms will probably require quarterly checks. The simpler the generator, the less there is to go wrong, and the less QC effort is required. For example, a single-phase, nonfluoroscopic generator without phototiming will normally require much less attention from the quality control and preventive maintenance programs than a three-phase, falling load, fluoroscopic generator with phototiming.

You must decide from your experience how frequently you should check the rooms and how often preventive maintenance and calibration will be required. Every x-ray generator and imaging system should be calibrated and thoroughly checked at least once a year (Joint Commission on the Accreditation of Hospitals, 1980). QC checks should be carried out immediately following annual calibration and preventive maintenance as well as at 6-month intervals between annual invasive servicing. In addition, QC checks should be made immediately after any servicing that may affect the quality of images or the radiation output of the equipment. These checks need not be as extensive as those carried out in between the invasive calibration and preventive maintenance tests (for example, if a collimator has been removed then the half-value layer and collimator alignment should be checked).

WHAT SHOULD BE EVALUATED?

Simply stated, everything that affects the quality of the radiograph, the dose to the patient or staff, the safety of the patient and staff, and the comfort of the patient should be checked as part of the quality control program. However, you should determine the parameters to be tested or checked on the basis of the usage of the particular room.

Only those functions required for a particular room need to be checked on a regular basis. For example, if an x-ray generator is only used between 65 and 100 kVp and at 200 and 400 mA there is no need to check the entire range of kVp values, which may be from 30 to 150 kVp, nor to check all of the mA stations, which may range from 25 to 1000 mA. (If this is indeed the case, you should ask why a 150-kVp, 1000-mA generator was purchased in the first place since a less expensive unit would have been sufficient.) This makes the job of the QC technologist easier, as well as that of the service engineer, while providing an additional benefit—the possibility that you will get better generator calibration over the more limited range, allowing for the matching of x-ray outputs from room to room with all of the inherent advantages. As in the above example, you should also evaluate the stations on either side of the useful range, e.g., from 60 to 120 kVp and from 100 to 600 mA.

IN-HOUSE EQUIPMENT SERVICE?

For the best possible quality assurance program, and for a significant savings in service costs, every department with 5 to 15 or more rooms of x-ray equipment should consider establishing their own in-house service program. Smaller facilities should consider time-sharing the services of an x-ray engineer.

In terms of cost, in-house service is a real bargain. Most manufacturers are charging between $50 and $60 per hour (door-to-door) for service plus parts. This means that a service call that takes the vendor's engineer approximately 1 hour will cost you $55 plus the cost of travel time, say ½ hour each way, for a total cost of $110. In addition, most firms charge mileage at 20¢ to 30¢ per mile plus a 50% premium for work on weekends or after normal working hours. Most firms charge approximately 7% of the *replacement* cost of the equipment for a service contract, although this may include some parts. However, a service contract does not include overtime, for which the customer is billed the 50% premium, nor does it include special modifications.

Obviously in-house service has a significant cost advantage over vendor-supplied service. However, there is another major advantage that is often overlooked. If you have your own in-house engineer, he or she will become intimately familiar with all of

your equipment and learn the quirks of each individual piece. In addition, the engineer will be available to assist in other projects when not busy repairing equipment. More importantly, he or she will be available at all times on short notice for equipment breakdowns and to repair minor nuisance items for which you would not want to call in a vendor's service engineer.

Another advantage of in-house service, which has become apparent in our facility, is the reduction in staff required to maintain the quality control program after a period of time. We are able to maintain the quality and service of our 173 rooms of equipment with three full-time quality control technologists, 25% of the effort of a physicist, and 7 service engineers. This is partly due to the fact that all of the calibration of all of the equipment is maintained within very tight tolerances from the day it is installed. Consequently, we carry out QC checks on our general radiographic equipment every 9 months, while carrying out preventive maintenance every 18 months, unless intermediate checks indicate otherwise. In some instances, certain types of equipment will require additional calibration, preventive maintenance, and QC checks. This is why it is necessary to start out a QC program with more frequent checks than may be necessary after all of the problems are corrected and the program is functioning smoothly.

Find out how much your department paid for x-ray equipment service last year and consider the possibility of an in-house service program. You will surely realize a cost savings while benefiting from minimum downtime, better equipment calibration, and better maintenance.

2 EQUIPMENT AND MEASUREMENT TIPS

WHAT EQUIPMENT IS NEEDED?

Actual equipment needs will depend on the size of the facility, the expertise of the individuals carrying out the tests, and the extent of the testing program (see Tables 2.1, 2.2, and 2.3). Note that the equipment needs should *not* be constrained by fiscal considerations. Although a complete collection of equipment as described in Table 2.3 may cost between $15,000 and $20,000, you should consider this in terms of the total investment of equipment in the diagnostic imaging department and the value of the services that can be provided with such equipment.

Most of the test equipment that we describe as part of our test procedures is available commercially. We do not mention manufacturers' names specifically since many firms make or market similar equipment, and it would be difficult to include all vendors. The Bureau of Radiological Health has published quality control catalogs (Burkhart, 1977, 1978) that list a large number of test items and vendors.

We have found it necessary, for one reason or another, to develop a few pieces of test equipment at our institution. This equipment is described in detail in the Procedures sections so that the reader can reproduce it. One of these pieces is our patient equivalent phantom (PEP).

Table 2.1. QC tools for a small facility

Sensitometer
Densitometer
Thermometer
Collimator alignment template
Phantom or step wedge
Simple instructions on how to use phantom to check linearity, compare rooms, and evaluate fluoroscopic images
Screen-film contact mesh

Table 2.2. QC tools for a medium-sized facility

Sensitometer
Densitometer
Thermometer
kVp measurement device
Collimator and beam alignment test tools
Dosimeter (direct readout preferable)
HVL aluminum
Star focal spot test target
Tomographic phantom
Synchronous or electronic timer test tool
Phantom (patient equivalent and mammographic)
Mesh resolution pattern
Low-contrast test tool
High-contrast lead resolution pattern
Screen-film contact mesh

The patient equivalent phantom is based on a design for a phantom by the American National Standards Institute (ANSI) for the testing of photosensitive radiographic materials and photographic processing (American National Standards Institute, 1980). Its construction is based on transmission measurements at various kVp values, and has been modified so that the absolute transmission as well as the spectral transmission best simulates that from an actual patient, using readily available and inexpensive materials.

Table 2.3. QC tools for a large or extra-large facility

Sensitometer
Densitometer
Dosimeter (some have time duration option)
Full range of dosimeter chambers
Collimator and beam alignment tools
kVp test device
HLV aluminum
1.5° and 2° star focal spot patterns
Pinhole camera
Tomographic phantoms
Phantoms (full range of body part phantoms, uniform density phantoms, and resolution and contrast evaluation phantoms)
Step wedges
Full range of lead resolution targets
Mesh resolution patterns
Low-contrast test tools
Screen-film contact mesh
Oscilloscope
Scope camera
Output detector
Video waveform monitor
Video signal generator
Photometer
General purpose tools
Chart recording thermometer
Digital thermometer

The PEP, its specific dimensions, and materials are shown schematically in Figure 2.1a. It consists of six slabs of plastic (polymethyl methacrylate, also known as Plexiglas or Lucite) each 1 inch (2.5 cm) thick by 12 inches (30.0 cm) square. The six slabs are arranged in pairs so that the PEP actually is three phantoms in one:

1. Skull, abdomen, and pelvis phantom—consists of the chest phantom with an additional 2 inches (5.0 cm) of plastic added in the air space of the chest phantom (Figure 2.1b).
2. Chest phantom—consists of a 1-mm thick sheet of aluminum sandwiched between two slabs of plastic together with a second sandwich similar to the first but with a 2-mm sheet of aluminum (Figure 2.2a). [***Note:*** Type 1100 aluminum should be used.] When this is arranged with a 2-inch (5.0-cm) air gap between the two sandwiches, as shown in Figure 2.2a, a typical chest is simulated for testing purposes.
3. Extremity phantom—consists of a 2-mm sheet of aluminum sandwiched between two slabs of plastic (Figure 2.2b).

As mentioned before, the PEP was chosen since it provided spectral and absolute transmissions that closely simulate patients. We have found, for example, that the pelvis phantom simulates a 21-cm patient abdomen. In addition, its simple construction and relatively low cost make it available to most institutions. We should note that it is necessary to obtain a phantom of these dimensions, especially the 12×12 inch (30.0×30.0 cm) dimensions, to properly simulate the patient and the scatter generated by the patient.

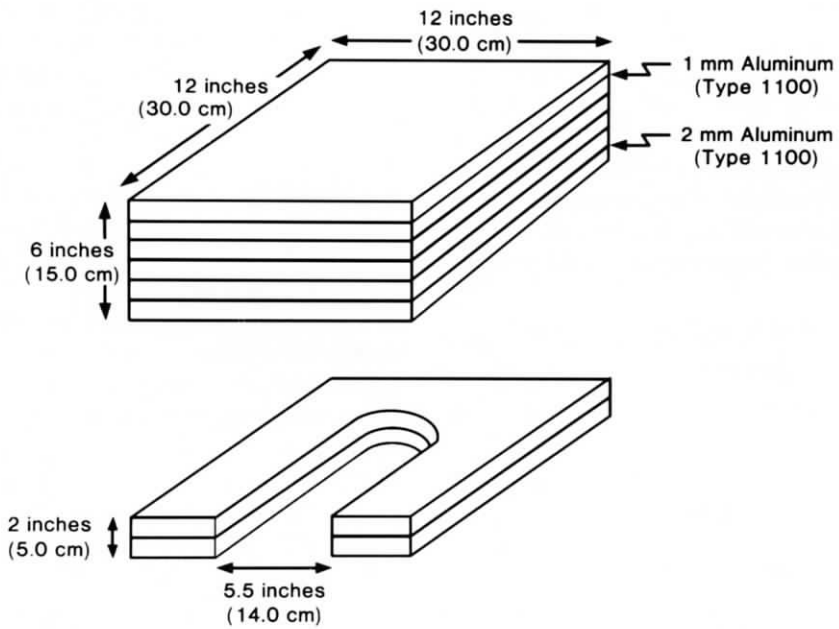


Figure 2.1a. Schematic drawing of the homogeneous patient equivalent phantom (PEP). The phantom and base, made of acrylic and aluminum, are used extensively in a quality control program.

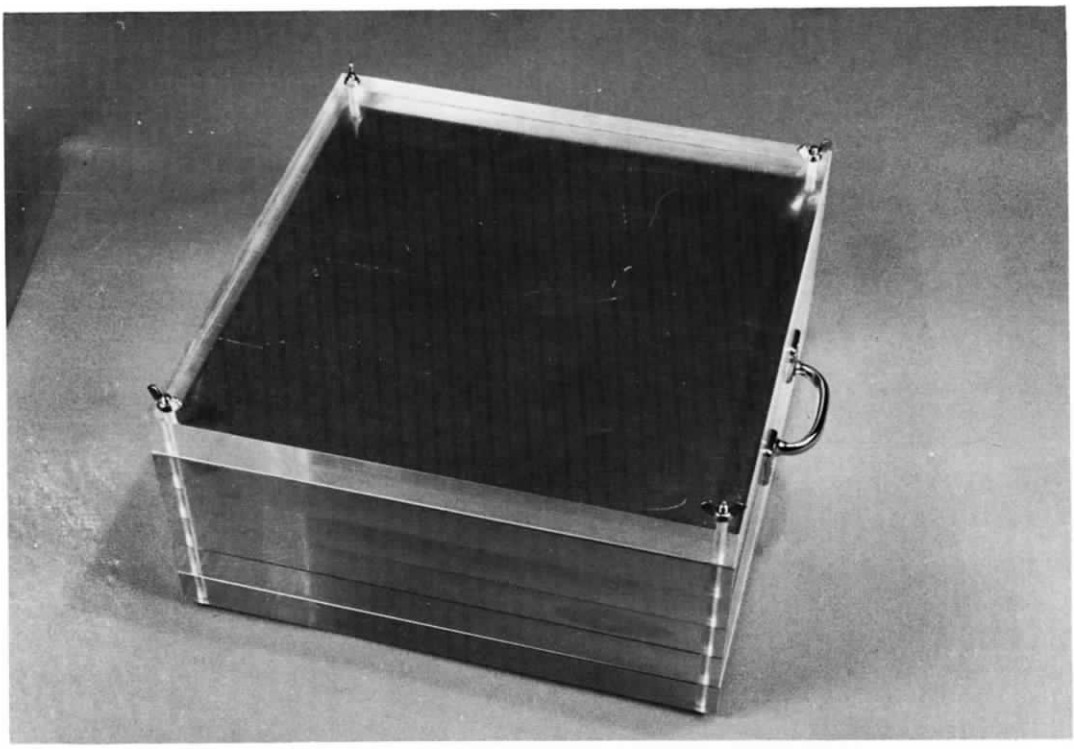


Figure 2.1b. Basic PEP, which is used to simulate the abdomen, skull, and pelvis.

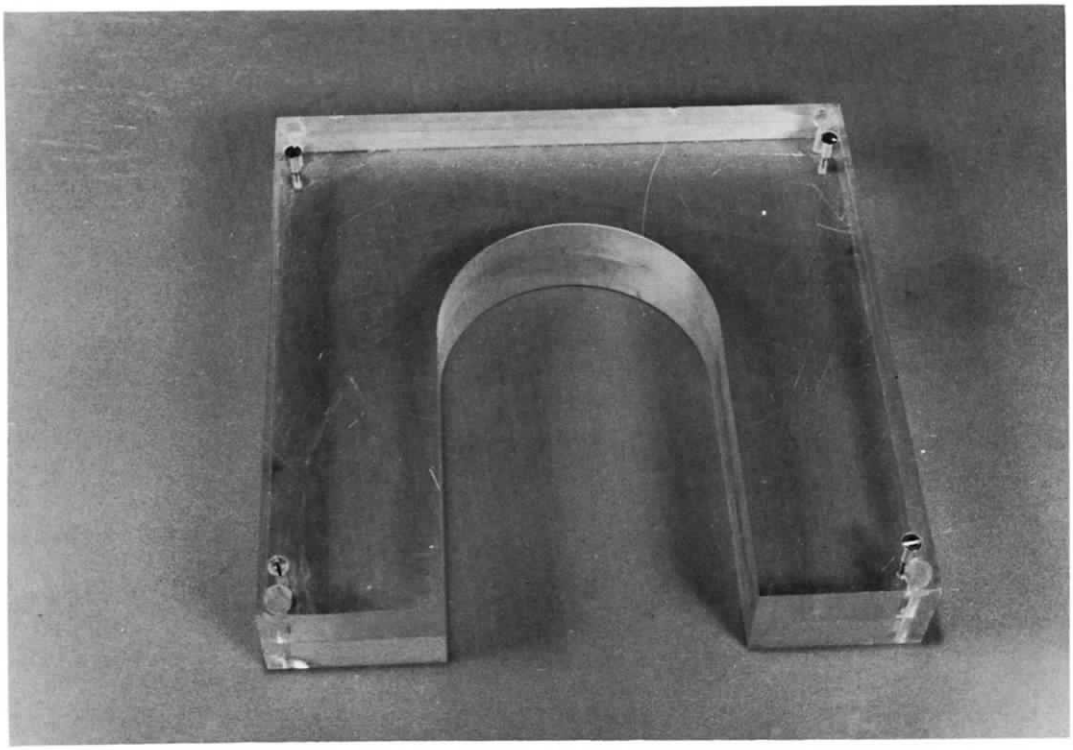


Figure 2.1c. Base for the PEP, which is used when dosimeter readings are to be made under the phantom.

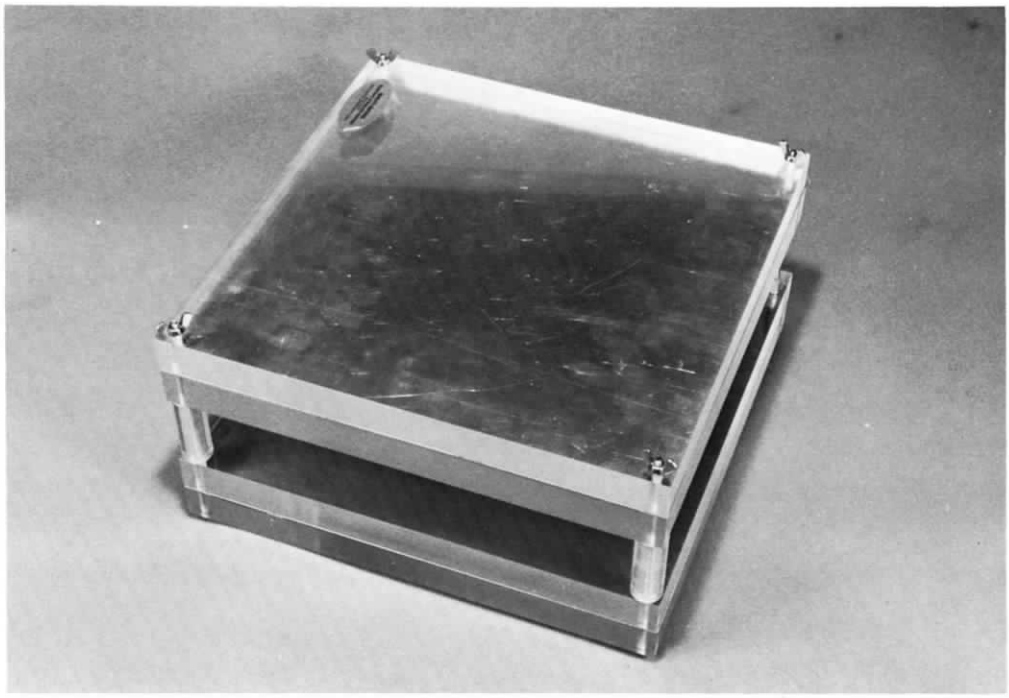


Figure 2.2a. PEP for chests and extremities. The basic PEP can be modified to provide a phantom that simulates the chest and extremities. The chest phantom is similar to the basic phantom, but two slabs of acrylic [2 inches (5 cm)] are removed from the center. A 2-inch (5-cm) air gap is left between the remaining layers.

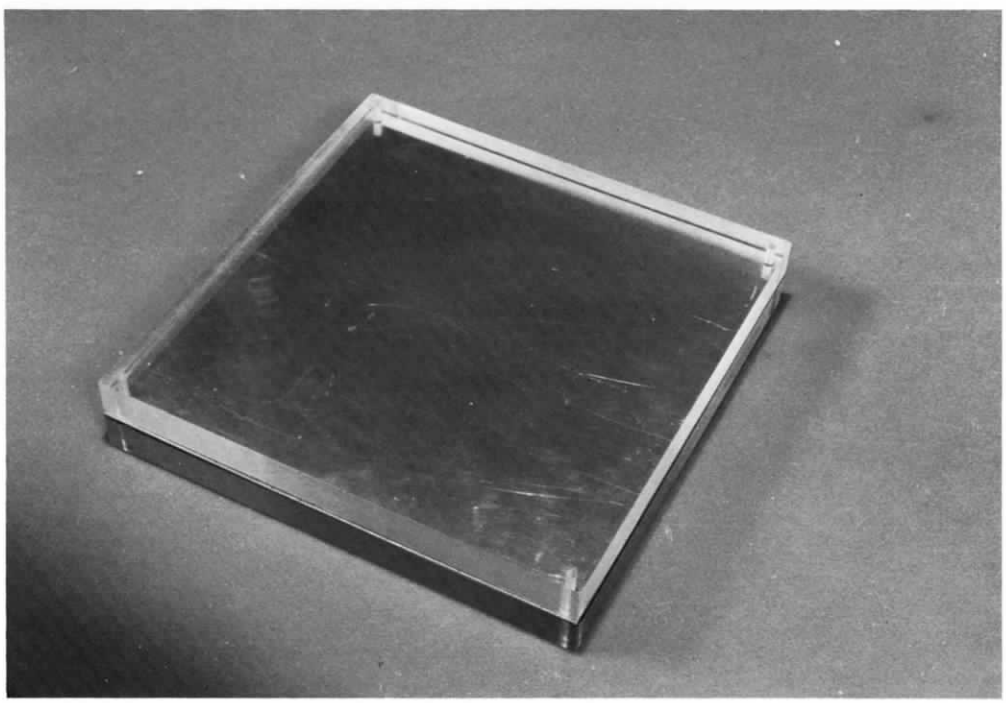


Figure 2.2b. The extremity phantom consists of a 2-mm sheet of type 1100 aluminum sandwiched between two 1-inch (2.5-cm) sheets of acrylic.

In addition to the PEP, we have developed a similar phantom containing several test objects that allows us to provide quantitative measurements of an imaging system as well as provide the clinical radiologist with objects to which he can relate (Figure 2.3). As can be seen in Figure 2.3a, it contains bone, catheters, simulated low-contrast "stones" in contrast media, steel wool, resolution targets, and a step wedge in a circular configuration. These are placed at various levels, as shown in Figure 2.3b. Of particular importance is the construction, type, and placement of the resolution targets. These contain frequency patterns to 5 cycles/mm since the large majority of imaging systems are limited to this level in the clinical situation, especially with the scatter produced by the phantom. Two of these, 0.10 mm and 0.01 mm thick, are placed on the bottom side of the phantom and allow determination of the high and low contrast resolution of the image recording system. The third, 0.10 mm thick, is placed on the top of the phantom and allows determination of the amount of unsharpness introduced by the focal spot and screen-film system in combination.

When we refer to the PEP, we will be referring strictly to the skull, abdomen, and pelvis phantom without any objects included, unless specifically noted.

DOSIMETERS

A dosimeter, properly understood and used, is an important tool in a quality control program. It is needed to determine the half-value layer (HVL), to determine how well a generator is calibrated (in terms of the mR/mAs measurements), and to measure the maximum and standard fluoroscopic exposure rates. A dosimeter can also be used to measure the attenuation of grids, tabletops, or any other item in the x-ray path, and it is beneficial in evaluating new products such as screens and films.

There are many factors that must be considered in the use of a dosimeter. There are basically three types of radiation measurement instruments (Figure 2.4). The survey meter is designed for measuring low levels of radiation such as those in an isotope lab or in evaluating x-ray exposure room shielding. This device is not suitable for quality control purposes. Pen dosimeters are sometimes recommended for quality control purposes, but we feel that they have many shortcomings that render them all but useless for an effective QC program. General purpose dosimeters with ionization chambers are the most expensive type of radiation measurement devices and the best for quality control purposes.

Dosimeters can be used with ionization chambers designed for specific purposes (Figure 2.5). Small volume chambers (less than 20 cc) are designed for high exposure rate measurements, e.g., high kVp, high mA, and short exposure time with measurements being made in air. These chambers must also be used with most dosimeters for the measurement of exposure times if that feature is available on the dosimeter. Large volume chambers (greater than 50 cc) are designed for lower exposure rate measurements such as low mA, low kVp, or heavily attenuated x-ray beams, e.g., for measuring the exit beam exposure behind a phantom, or the exposure in the Bucky tray where the exposure to the screen-film combination is on the order of 1 mR. These chambers are usually unsuitable for the measurement of exposure times because of their capacitive characteristics. Another type of ionization chamber is designed for use in mammography and has an extremely thin entrance window. This thin window is necessary to avoid the attenuation of the soft radiation used in mammographic applications. Finally, there are special chambers designed for CT applications. These are small, pencil-shaped chambers designed for insertion into CT phantoms.

All chambers have two limitations of which the user must be aware—energy and rate dependence. The use of the chambers for x-ray energies or rates other than those for which they were designed will provide confusing, meaningless results. The energy dependence is specified in terms of the keV range over which the calibration is within a certain percentage of the true value (usually ± 5%). For example, most dosimeters for diagnostic purposes are within ± 5% calibration over the range of 30 to 120 keV. (The effective keV of the beam is ½ of the kVp, so if you want to use a chamber that is calibrated from 30 to 120 keV, your measurements should be limited from 60 to 240 kVp.) The rate dependence of chambers is quite important since most diagnostic x-ray exposures will exceed the rates allowed for many chambers. The rate dependence results in readings lower than you should obtain since recombination of the ionized air and electrons occurs in the chamber (the dosimeter measures the amount of ionization), resulting in a low, false reading.

The entire volume of the ionization chamber must be irradiated to obtain proper readings, with the exception of the CT chamber. In the latter case, a correction factor is supplied with the chamber to assure proper readings.

Dosimeters are delicate, sensitive, electronic instruments and must be treated with tender loving care. Ask your physicist to go over the operation of

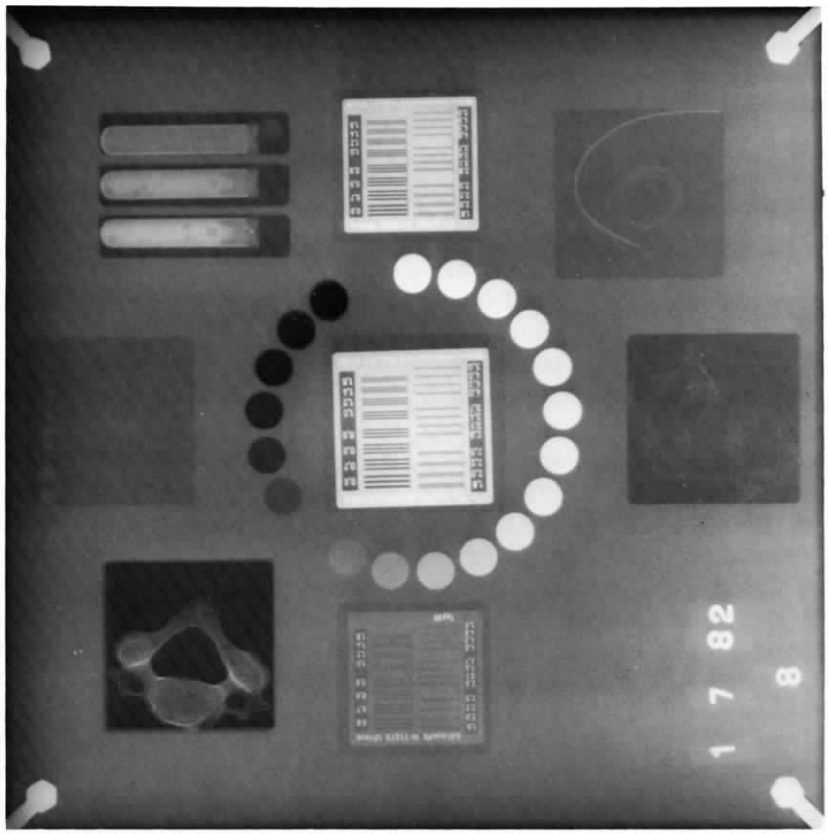


Figure 2.3a. Patient equivalent phantom containing special test objects. A radiograph of the phantom containing test objects shows that both quantitative and qualitative judgments can be made about image quality.

the dosimeter with you and explain all of the precautions of which you must be aware. Like any sensitive electronic instrument, dosimeters and their associated ionization chambers require recalibration on a regular basis. Most manufacturers offer recalibration, repair, and preventive maintenance services for a reasonable fee. We recommend that every dosimeter and chamber be serviced and recalibrated on an annual basis.

QUALITY CONTROL FORMS AND CONTROL CHARTS

As we discuss in Chapter 3, all of the data collected in a QC program should be maintained in a way that allows you to review each measurement over the history of the equipment. We have provided all of the forms and control charts that we have developed for our QC program in Appendix A. (These may be copied for individual use without the permission of the authors or publisher, but they may not be copied for resale.) Keeping these forms and control charts up to date will provide you with the appropriate information for troubleshooting and also for determining the reliability of each piece of equipment, a real asset for a radiology department.

SERVICE REQUEST FORM

Also in Appendix A is a copy of a service request form that we use to request in-house service. This is a four-part form that is initially filled out by the individual detecting the problem—the staff technologist, x-ray supervisor, or QC technologist. The first copy is retained by the x-ray supervisor as an indication that service is required and the three remaining copies are given to the service engineer. Upon completion of the service work, the engineer gives one copy to the x-ray supervisor indicating that the work is complete. Another copy is placed in the QC room log by the service engineer to alert the QC technologist that service has been performed, and the final copy is maintained by engineering in their room file to indicate what service has been carried out in a particular room.

Prior to a room QC check, or any other time the QC technologist goes into an x-ray room, the service

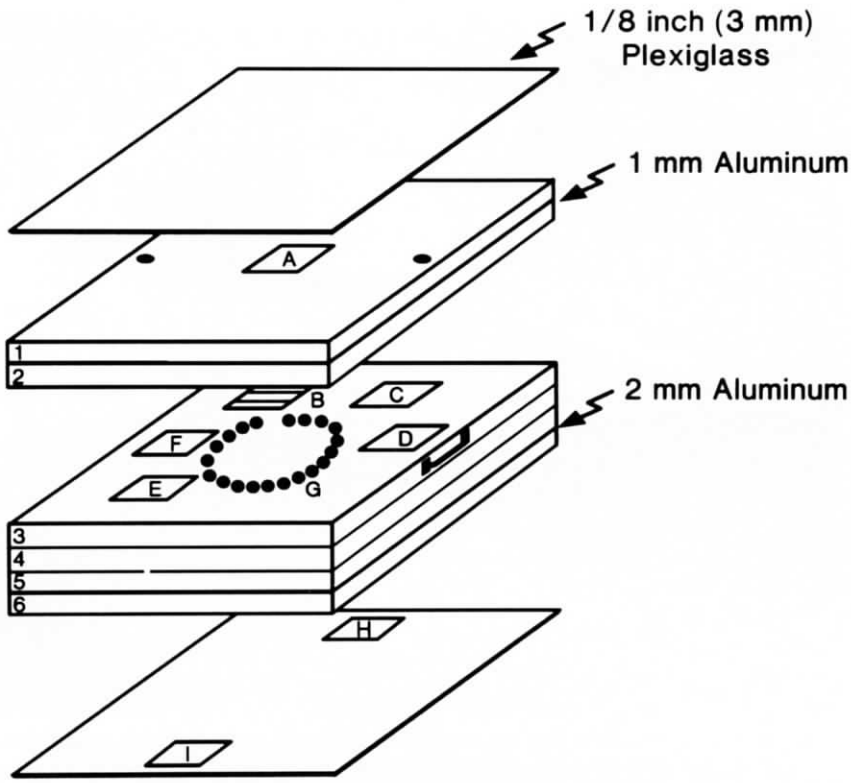


Figure 2.3b. The placement of the objects is important. Objects are placed in specific layers as follows:

Layer 1: A 0.10-mm lead resolution target *(Item A)* provides information concerning the focal spot characteristics since this is closest to the x-ray source. This layer also contains markers indicating the anode and cathode ends of the image.

Layer 3: This layer contains: dilute contrast media in small plastic vials with several plastic beads in the contrast media *(Item B)* to simulate a gallbladder with stones; a cutout with short pieces of catheter material *(Item C);* a cutout containing steel wool *(Item D);* a deeper cutout containing a portion of a vertebral body *(Item E);* a cutout containing various sizes of plastic beads *(Item F);* and a step wedge *(Item G)* made by inserting aluminum rods of various lengths to obtain film densities lighter than the surrounding material and by drilling holes into the acrylic to obtain film densities darker than the surrounding material.

Layer 6: On the underside of layer 6 there are two lead resolution targets *(Items H and I);* one is 0.01 mm thick, providing a low-contrast image to assist in determining the effects of quantum mottle, and the other is 0.10 mm thick, providing a measure of the resolution of the screen-film system.

request copies in the QC log are reviewed and summarized in the maintenance log (a permanent part of the QC room log). These copies are then discarded. This procedure ensures that the QC technologist is aware of what service has been performed. However, if the service engineer has performed any work in the room that may affect image quality or the x-ray output of the system, he immediately notifies the QC technologist upon completion of the service work. The QC technologist then carries out the necessary tests to assure that integrity of the equipment and image quality and patient exposure are optimal.

QC EQUIPMENT CART

The amount of QC test equipment needed, especially for medium- or larger-sized facilities, can present some difficulty in transporting it to the room to be evaluated. To simplify the movement of this equipment around the department, and to assure that all of the equipment is available in the room when needed, we have developed an equipment cart that contains all of the necessary test equipment and tools (Figure 2.6).

Since several of the pieces of test equipment require electrical power, and since most x-ray rooms usually have a minimum of electrical outlets, we have mounted a multiple outlet box with an integral circuit breaker on the cart (Figure 2.7). This means that only one electrical connection must be made when the QC technologist enters the room, with all of the equipment being powered from the multiple outlet box.

Since film, cassettes with film, and Polaroid film are carried on the cart, and it is in the room during

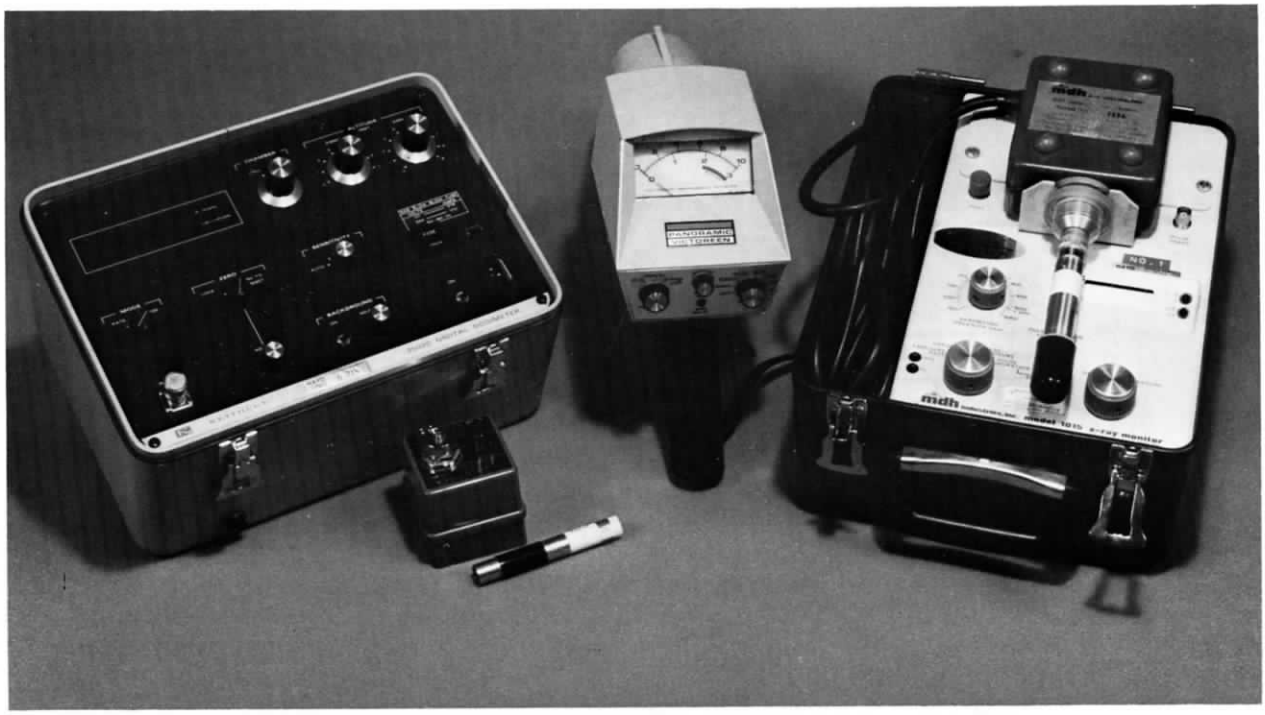


Figure 2.4. Radiation measurement equipment. The survey meter *(center)* is not suitable for dosimetry or QC purposes. A pen dosimeter, shown in the lower left with its charger-reader, can be used for limited purposes, but because of its inherent limitations we do not feel it is accurate enough for QC purposes. Direct readout dosimeters *(on the left and right)*, although somewhat costly, are essential for reliable and accurate dosimetry and for a good QC program.

Figure 2.5a. For QC purposes we recommend a direct readout digital dosimeter that digitizes the signal at the ionization chamber. Three chambers are necessary for specific purposes: a thin-windowed chamber for mammography *(left)*; a large volume chamber for use under phantoms and in making measurements at low radiation levels *(center)*; and a small volume chamber for making measurements at high radiation flux levels as well as monitoring the x-ray waveform *(right)*.

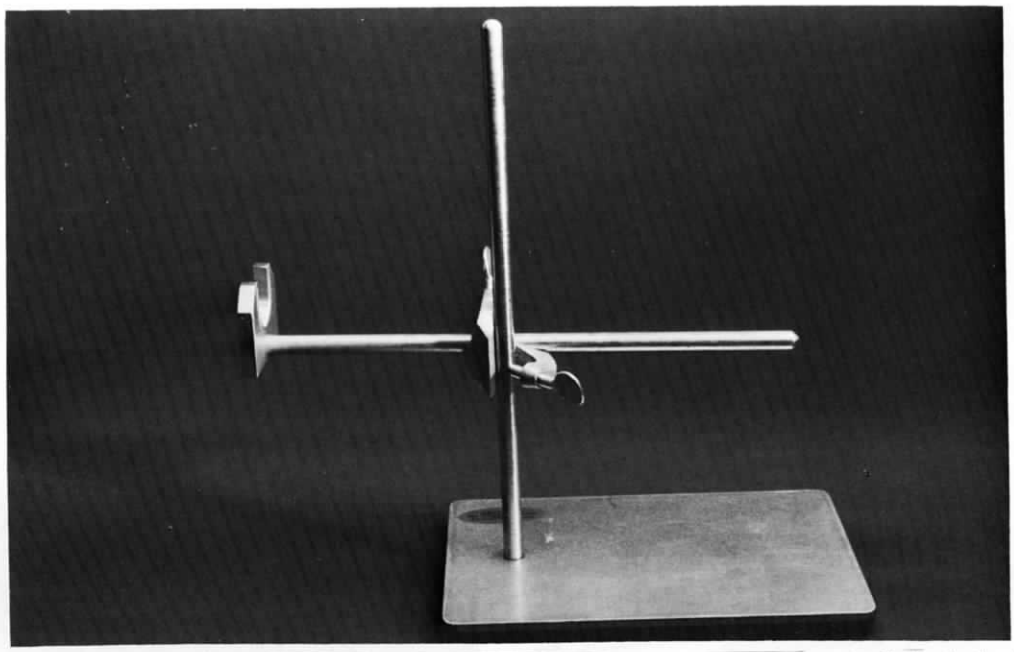


Figure 2.5b. Although not essential, a stand can be constructed with a lead-weighted base to hold the dosimeter at the appropriate level for measurements.

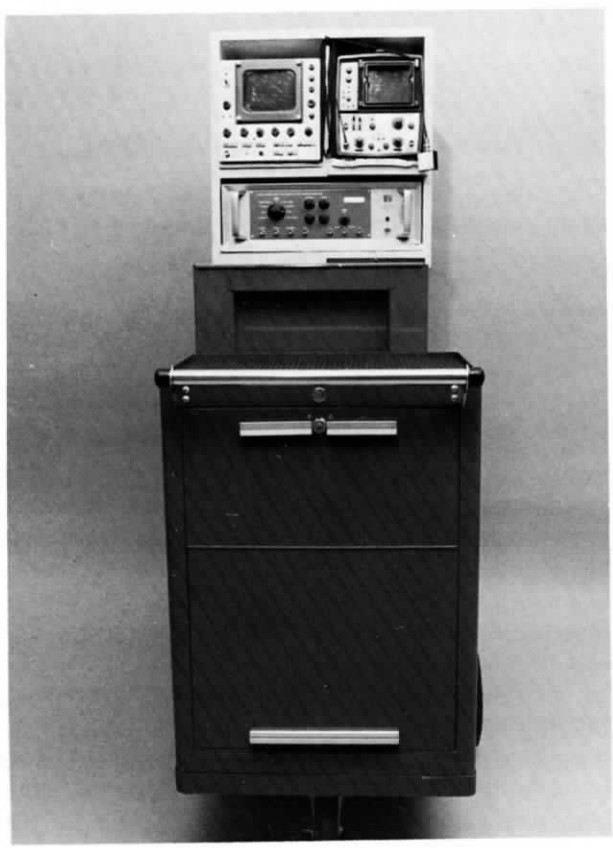


Figure 2.6a. Quality control equipment cart. It is convenient to have all of your equipment on one cart so that it is available when you are working in a room. The locked section contains tools (screwdrivers, pliers, etc.) and the readout section of the dosimeter. The rack on top was added to the cart to hold electronic test gear.

Figure 2.6b. All QC test tools are contained in the locked drawers and lower storage area (including the PEP). One small drawer is lead-lined so that film can be stored in the cart without risking film fog. The flat area to the left provides a writing area. Various ionization chambers are stored in one drawer, which has been lined with foam containing cutouts to fit each chamber.

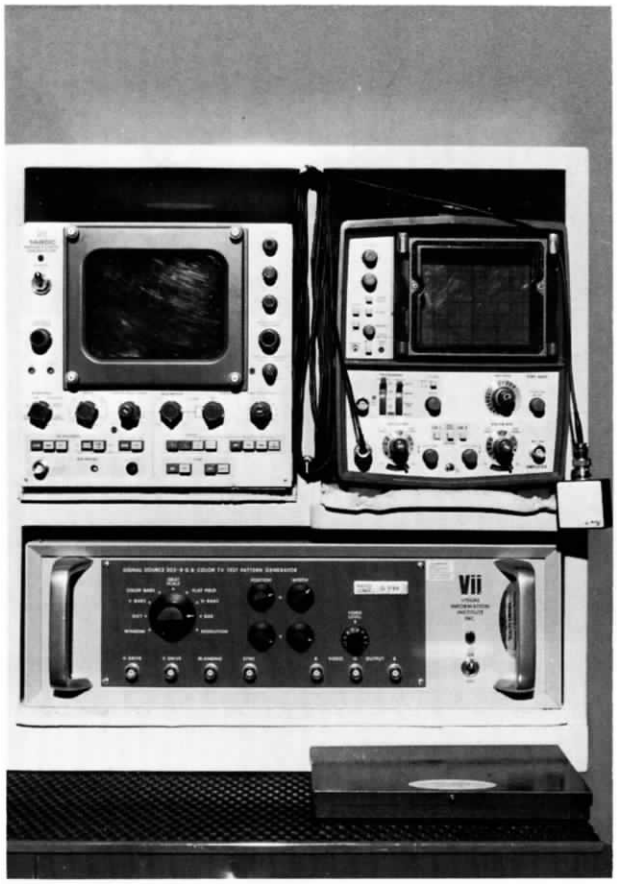


Figure 2.6c. Electronic test equipment includes a video waveform monitor *(upper left)*, a storage oscilloscope with a solid-state detector connected to it *(upper right)*, and a video signal generator *(bottom)*, all sitting on foam (for shock absorption) in a specially designed cabinet. Note also the lead letter and number identification kit on the lower right.

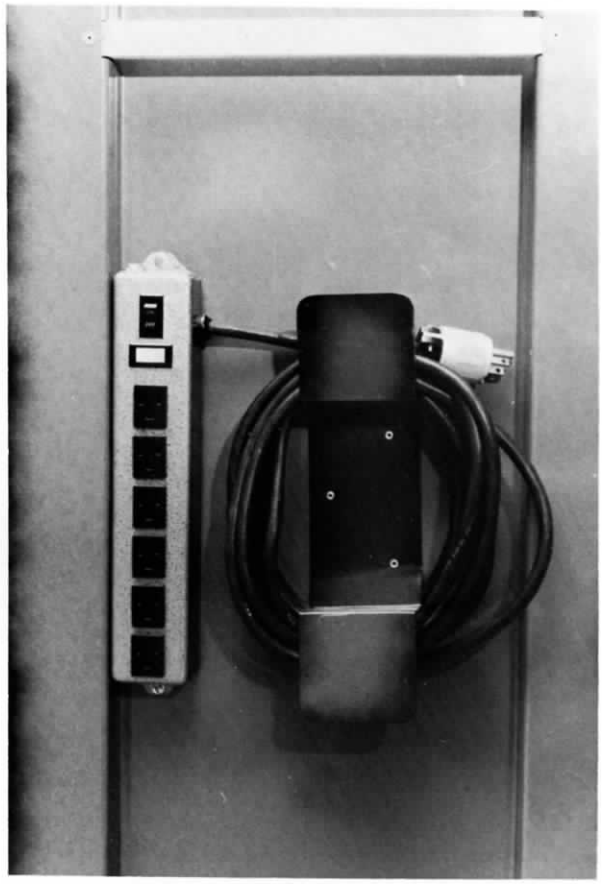


Figure 2.7. Multiple outlet box. Since most radiographic rooms do not have sufficient outlets to support all of the test gear, and to make set-up easier and quicker, a multiple outlet box with a switch and circuit breaker is mounted on the right side of the cart (relative to Figure 2.6b). In addition, an extra-long electrical cord is provided so that the cart can be positioned anywhere in the x-ray room.

x-ray exposures, one drawer of the cart is lead-lined to prevent film fog.

A writing surface is also provided on the cart, allowing the cart to be placed just inside the control booth door. This allows the technologist to have the dosimeter and oscilloscope available near the control panel and reduces the number of steps required in checking out the x-ray system.

HEEL EFFECT

Heel effect is the term given to the change in intensity of the x-ray beam along the anode-cathode axis of the x-ray tube. It varies with the anode angle (being greater for shallow angle tubes) and with the distance from the x-ray source. The intensity of the x-ray beam will be lowest on the anode side of the x-ray beam, increasing to its highest value somewhere past the central ray and dropping off again toward the cathode side of the beam (Figure 2.8). With a greater source-to-image distance (SID), the effect is less significant since you are only using the central portion of the beam. For example, at a 40-inch (100-cm) SID, the intensity of the beam will decrease to 55% at the anode end of a 17-inch (43-cm) field and to 98% at the cathode end of the same field. At a 72-inch (180-cm) SID, the intensity of the beam will decrease to 78% at the anode end of a 17-inch (43-cm) field and increase to 107% at the cathode end of the same field. (All measurements are normalized to 100% under the central ray.)

Whenever possible, radiation measurements should be made with the ionization chamber under the central ray. If measurements cannot be made in

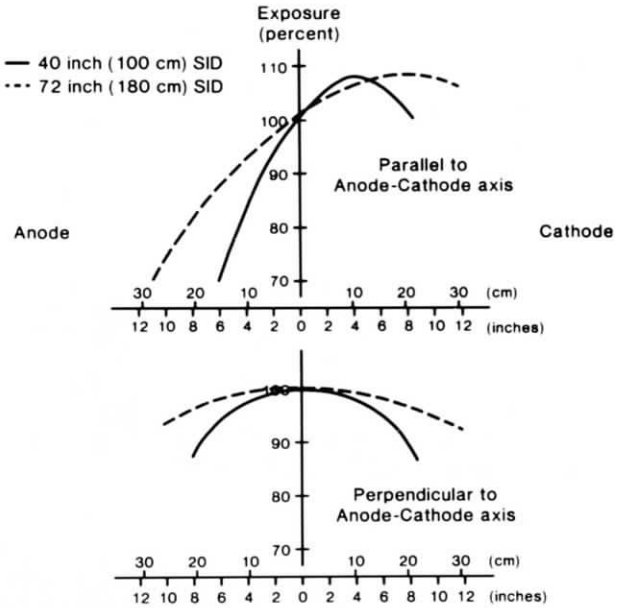


Figure 2.8. The heel effect can cause difficulty in making radiation measurements. Considerable variability will be noted as the ionization chamber is moved parallel to the anode-cathode axis, expecially with a 40-inch (100-cm) SID. Variation is not nearly as significant perpendicular to the anode-cathode axis, but it is still present.

this manner, always make each of them with the ionization chamber positioned on the same side of the beam (e.g., on the cathode side), and with the chamber the same distance from the central ray.

Whenever you are making measurements from film, such as in the use of the kVp cassette, the dimension of interest should be placed perpendicular to the anode-cathode axis. Step wedges should be placed in this orientation also since the change in intensity is much less than along the anode-cathode axis (Figure 2.8).

In clinical practice, the heel effect can be used advantageously. For example, in a radiographic room used mainly for abdominal procedures, the x-ray tube should be mounted so that the cathode side is toward the patient's head, placing the highest intensity point of the beam over the thicker portion of the abdomen. On dedicated chest systems, the x-ray tube should be mounted with the cathode end of the beam toward the patient's feet. Consideration should be given to the position of the x-ray tube whenever a new system is installed or a tube is replaced so that the heel effect is used to the best advantage.

3 BASICS OF QUALITY CONTROL

OBJECTIVES OF A QUALITY CONTROL PROGRAM

The major objective of the quality control program is to detect changes in image quality that may affect diagnosis or cause changes in the radiation exposure to the patient before they become significant and, most importantly, to request service or calibration of the imaging systems before the radiologist comments on the loss of image quality. In other words, we want "...to provide quality that is satisfactory, adequate, dependable and economic" (Thomas, 1973).

Let's examine those four words in detail and see what they really mean.

Satisfactory—we want to assure that the quality of the images fulfills the needs of the radiologist, i.e., that the clinical images are satisfactory.

Adequate—the quality of the images should be sufficient for a specific requirement, i.e., the quality is adequate. Note that we very specifically indicate here that the quality is sufficient for a *specific* requirement. This is important in that less expensive systems may be utilized where appropriate. For example, the image intensifier for GI examinations need not be of as high a quality as one used for cardiac catheterization (in the former case, the system is limited by the TV chain and in the latter case, if you are recording the images on cine film, the intensifier limits the quality of the images).

Dependable—the quality should be consistent, the density and contrast should be the same on any day the exam is carried out, and the radiologist should be able to compare films from one day to the next or from year to year without having to "read through" differences in the images due to changes in the equipment, image quality, etc.

Economic—In addition to all of the above we would like to keep the costs of operating a radiology department as low as possible. Along these same lines, we want to select the equipment or materials that will give us the best examination for the specific situation. Why purchase a $75,000 three-phase, falling load, phototimed generator for a limited-purpose situation such as an operating room when a $15,000 single-phase generator will do the same job? In addition to the equipment and materials being economic, you must remember that the quality assurance and control programs should be as economic as possible, but this doesn't mean cutting corners when it comes to purchasing QC equipment. Good QC equipment will save considerable time in a quality control program and is well worth the investment.

In summary, the major objective of the QC program is to maintain the quality of clinical images at an optimum level, at a reasonable cost, and to request service or calibration of the equipment *before* the clinical quality of the images deteriorates. Consequently, the measurements you make must be accurate, reproducible, and sensitive enough to detect changes less than those that would be objectionable to the radiologist.

MEASUREMENTS AND CONTROL CHARTS

In a QC program we want to deal with data that are objective and that can be easily quantitated. In other

words, we don't want to deal with one individual's opinion of whether the contrast is sufficient; we prefer to measure the contrast and then determine from past experiences whether the contrast (the numerical value) is optimum. This may create some difficulty since personal preferences of radiologists vary, but the best solution to this problem is to work to the requirements of the most critical radiologist. If you satisfy the most critical individual, you will satisfy all of the radiologists.

All measurements you make will contain two types of errors—systematic and random. Since we want to use these measurements to detect slight changes in the parameters we are measuring (changes that are less than those that are visually apparent), you must exercise extreme caution to assure that the measurements are made properly and made *in the same manner each time.* If the radiation output is to be measured at 100 cm, this means that the center of the ionization chamber is to be 100 cm from the x-ray focal spot and not 99 or 101 cm. Errors of this type, errors introduced by the QC technologist making the measurements, are systematic measurement errors and must be avoided at all costs. Also in the category of systematic errors would be differences in measurements made by two different QC technologists, even though the measurements made by each may be consistent. (For example, one technologist measures the exposure with the center of the ionization chamber 100 cm from the focal spot and the other measures the exposure with the top of the chamber 100 cm from the focal spot.) We will try to point out the major sources of systematic error in each of the tests we describe, but we can't stress too strongly that you must do everything possible to eliminate all sources of systematic error.

Random errors are errors in your measurements over which you have no control. For example, you set up the dosimeter properly to measure x-ray exposure and make six exposures without changing any of the generator settings or moving any of the equipment and you get the following series of readings:

105 mR, 98 mR, 103 mR, 100 mR, 101 mR, 97 mR

Which of the readings is the true reading? They are all correct in their own way but there is an inherent, random variation in these six readings. The average value ($\bar{X}$) here is 100.7 mR.

One word of caution is appropriate here concerning the accuracy of measurements. The actual average value of these six readings is 100.666666666... mR. However, we will work with the rule of thumb that you carry only one additional digit along after the calculation beyond the significant digits displayed by the instrument. In the case of these six readings the dosimeter provided, at most, three significant digits so we will report the result in terms of four digits.

Now if we make six additional measurements and determine their average, we will find that the average values also vary because of random variation. How can we cope with this variation so we know that the results we get are real and that changes we are seeing are due to changes in the equipment and not to random variations in the measurements? In order to help us sort out these problems, we will use control charts for logging all of our data.

Control charts are the key and backbone of a quality control program. A control chart is a graphical means of recording data that allows for the easy inspection of those data from the present measurement back over the history of the control chart (Figure 3.1). Each measurement is recorded along the horizontal axis of the control chart as a function of time. For example, if we are making measurements on a daily basis, the increments on the horizontal axis are in terms of days. The vertical axis represents the numerical value of the measurement we are making. In

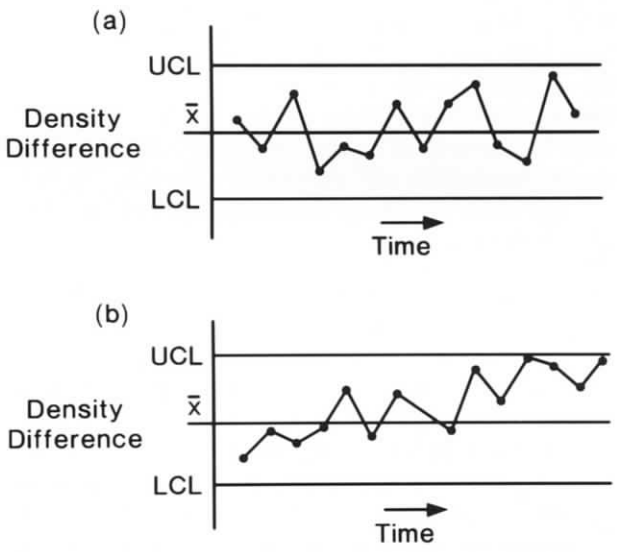


Figure 3.1. Basic control charts. Control charts are plots of numerical values with time. The data will contain inherent variation **(a)** and should oscillate around the operating level *($\bar{X}$)* and remain within the upper and lower control limits *(UCL* and *LCL).* Any time a single data point reaches or exceeds the control limits corrective action *must* be taken, although the test should be rerun to verify that the process is indeed out of control. Also, any time that a control chart shows trends (an increase or decrease in data over at least three data points) corrective action should be taken. The control chart in part **b** shows an out-of-control process since there is a steady increase evident over a long period of time—in fact, corrective action should have been taken after the fourth or fifth data point.

the example in Figure 3.1a, we are looking at the density differences from a daily photographic processor quality control program. Consequently, the values along the vertical axis represent the density differences we are measuring. There are three important numbers on this axis: the average value, the upper control limit (UCL), and the lower control limit (LCL). The average value, $\bar{X}$, is the value at which we would hope to find the density difference every day when we make the measurement. However, because of random variation, we really find that the measurement of the density difference seldom falls on the average value line, but oscillates around that value. How do we determine if the magnitude of these variations is acceptable and is indeed due to random error?

This is where the upper and lower control limits come into play. The control limits indicate the maximum and minimum values of the measurement that we will accept as normal random variation. If the measured value reaches or exceeds the control limits, then we must assume that a significant change has occurred in the operating level of the process. If a change has occurred, we then must *immediately* make a correction or take what is referred to as corrective action. In many instances, this will mean that we must call in a service man, change the chemistry, and so forth. Consequently, since corrective action may involve a considerable effort, it is always prudent to *make a second measurement* to verify the fact that your data have really reached or exceeded the control limits, and that the process is out of control. If after repeating the measurement the process is still out of control, then corrective action must be taken immediately. We cannot stress enough that **when the control limits are reached or exceeded, corrective action must be taken *immediately*.** Why make measurements and determine that something is not functioning properly if you are not going to do anything to correct the situation?

Another condition that you will encounter in the use of control charts is one in which all of the data points remain within the control limits but steadily increase or decrease (Figure 3.1b). This also indicates an out-of-control condition for which corrective action must be taken *immediately* since the control limits will be reached if the process is allowed to continue operating. This slow change in the process is known as "drift" and it is most frequently encountered in photographic processing.

Caution must be taken in determining if drift is occurring in the process. Normally, you must see at least three data points moving in the same direction, either upward or downward, before it is possible to determine if the process is really drifting. In other words, if you can draw a line through three data points as shown in Figure 3.1b and that line is moving upward or downward then the process is probably shifting and the problem should be investigated to determine its cause. Note that we stated that the problem should be investigated—in this case corrective action should be taken only after you determine the cause of the problem. If the cause cannot be ascertained, then the process should be monitored closely to determine if the drift was in fact real.

ESTABLISHING OPERATING LEVELS AND CONTROL LIMITS

The operating level of the control chart is the central line about which we expect our day-to-day measurements to fluctuate. In order to establish this level, we must know something about the measurements, about the process, and about the history of the process.

Let's take, for example, the operating level of an x-ray generator in terms of the kVp. This is quite simple since we know that when we set 80 kVp on the generator we want the measurements we make using the test cassette to indicate that we are indeed getting 80 kVp. We then must know something about the measurements so we know what each line above and below the operating level represents. Do we want the divisions to be in terms of ½ kVp? Since we know that we cannot measure the kVp more accurately than 1 or 2 kVp, then looking at ½ kVp changes would be meaningless. In this case, we will make each division equal to 1 kVp.

If we want to set up a control chart for a photographic processor, this becomes more difficult since there are no standards defining what density we should get on our film for a specific exposure. Consequently, we must know something about the measurements, about the process and about the history of the process (we already do—we know there are no standards!). We know in advance that the measurements cannot be made more repeatably than ± 0.01, the inherent limitation of the densitometer. We also know that measurements cannot be made more accurately than ± 0.02, a limitation associated with the instrumentation as well as the measurement process in general. Consequently, we will make each division equal to 0.02.

What about the operating level? To establish this, we must know something about the history of the process. In this case, we must put fresh chemistry and starter in the processor, allow the chemistry to equilibrate, and process a sufficient number of films [one hundred 14 × 17-inch (35 × 43-cm) films or the

equivalent of assorted sizes] to assure that the chemistry is stable before we can determine the correct operating level. This methodology is described in detail on pages 44–45.

Once the operating level and the divisions on the control chart are determined, these should be placed on the control chart (Figure 3.2). In addition, the upper control limit and the lower control limit values should be determined and recorded on the control chart, and indicated by a red line. The operating levels and control limits that we provide in this text are ones that are based on statistical analyses of QC measurements and that, through experience, we have found to provide the sensitivity to detect significant changes in the measurements we are making while not indicating changes in the process when they do not exist. You may wish to consult with your physicist and service engineer to determine if these operating levels and control limits are reasonable for your facility or if other levels may be more appropriate. However, it is important to remember that these levels and limits should be such that you can detect changes *before* they are visually apparent to the radiologist reading the radiographs. At the same time, you do not want the operating level set at an artificial level that is difficult or impossible to maintain, nor do you want the control limits set so close to the operating level that you are calling for corrective action unnecessarily. [***Note:*** The control limits can be determined on a statistical basis and your physicist may want to refer to a standard statistical textbook for information on how this is done (Crow et al., 1960; Rickmers and Todd, 1967)].

ROOM LOGS FOR QUALITY CONTROL

Next to control charts, room logs are the most vital part of a quality control program. The room log, kept in a single three-ring binder, consists of all of the control charts associated with a particular room, room inventories, maintenance logs, sample images, and so forth—all of the data needed for reference during a quality control check of a room (see Appendix A). (It may be useful to keep a duplicate set of logs in the quality control office for quick reference and to minimize the problems created as a result of a lost QC room log, although this means that both sets of logs must be updated during the QC check.) The items that should be maintained in the room log are listed in Table 3.1. Most items are self-explanatory, but special attention should be paid to those items noted below.

The "Quality Control Procedure" section of the room log may contain detailed instructions for carrying out the QC tests, but this is usually not necessary since all tests should be carried out in the same manner from room to room to assure that results are meaningful. However, detailed procedures for all tests should be maintained with the test equipment. It is necessary to note any deviations from normal procedures in this section and to indicate which kVp and mA stations, for example, are used for evaluation (normally only those stations that are used in a particular room, and adjacent stations, need to be checked on a regular basis). If deviations from the normal procedures are noted in this section, then this fact should be clearly indicated on the appropriate control charts so that anyone doing the tests or analyzing the data is aware that differences may exist.

The "Visual and Manual Quality Control Checks" are necessary checks of items in the room that may affect image quality or patient safety and comfort. These checks should be done by the QC technologists since they are not in the room every day and will be more alert to missing items and problems. This list may be modified to meet the individual needs of a department, but our experience has indicated that the same list should be used in almost every room in the department.

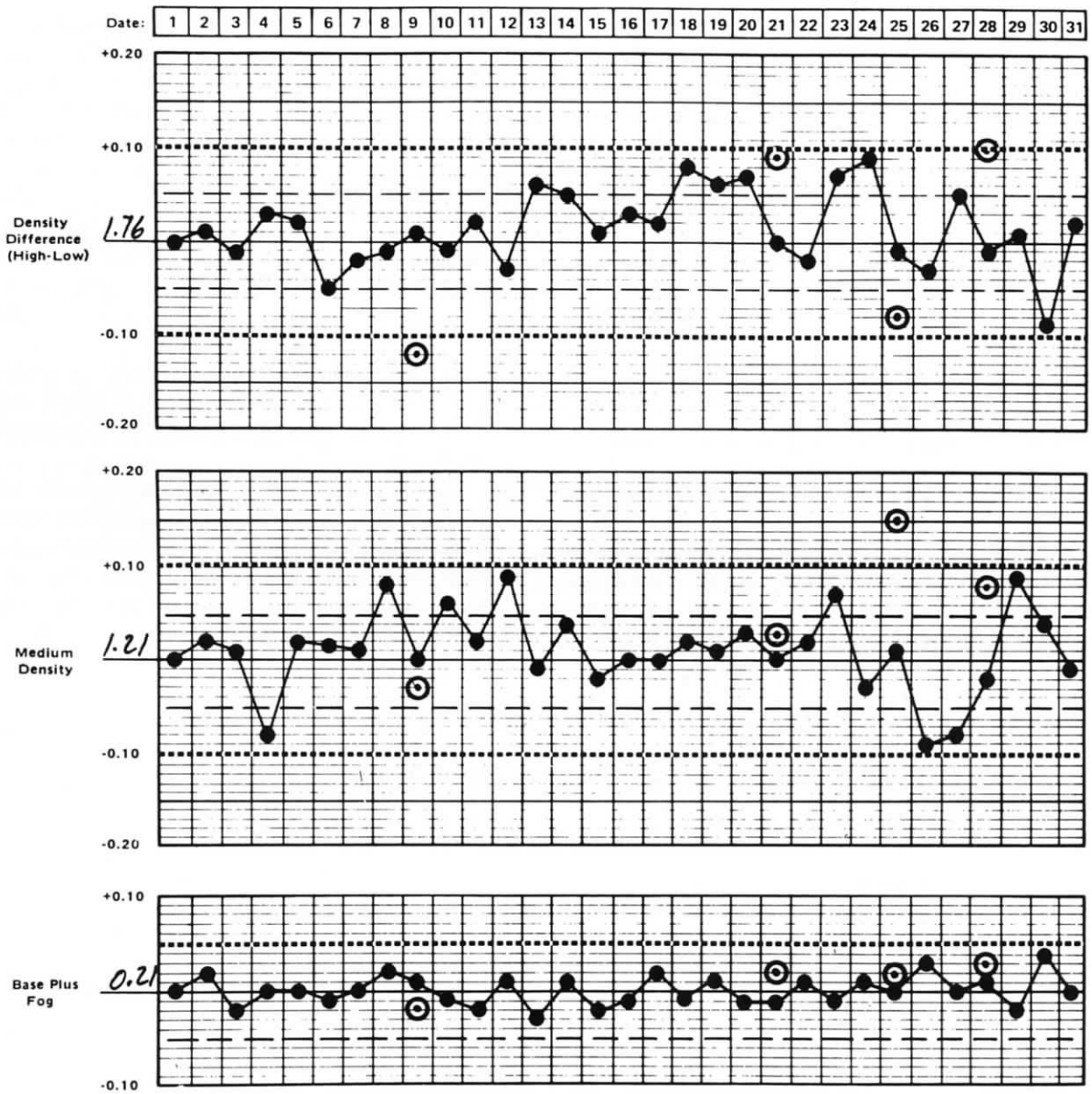
The "Maintenance Logs" are a very important part of the room log. Each time service of any type is performed on the equipment, an indication of this service should be noted in this log. You may wish to have the engineers leave a copy of the service form in the room log so the QC technologist can review the service forms and summarize them in the Maintenance Log, or you may have the engineers directly enter the information in the Maintenance Log. In either case, it is essential for the QC technologist to review the forms before carrying out the QC tests so he or she is aware of potential changes resulting from the recent service requests. The Maintenance Logs also provide a quick way to determine the amount of service that has been required on a specific piece of equipment in

Figure 3.2. Sample photographic processor control chart. Several important points are apparent on this control chart. The upper and lower control limits are emphasized with short dashed lines (normally, red lines for the control limits would be added to working control charts). Information concerning replenishment rates and chemicals temperature is recorded. Each time any single data point reaches or exceeds the control limits all of that test's points are plotted and then circled. The data points resulting from retesting after corrective action was taken are then plotted and connected to the previous day's data points. Also, the specific corrective action is noted in the "Remarks" section of the chart for future reference and assistance.

X-RAY PROCESSING CONTROL CHART

Department of Radiology

Processor: # 2 Angio Month: July 1982



REPLENISHMENT RATE

Date	Developer	Fixer
7/1	10	30
7/21	8	30

TEMPERATURE

Date	Developer	Wash
7/1	92°	87°
7/21	92°	87°

REMARKS

Date	Action
7/1	Hypo clear - OK.
7/2, 7/8	Racks cleaned
7/9	add 200 ml Rep
7/15	chem changed
	System cleaned
	500 ml starter
	Rep. tanks filled
7/21	Reduced Rep. Rate

Date	Action
	Processed 10 fully exposed 14x17's
7/25	60 watt Safelight bulbs fogged film
7/25	Racks cleaned
7/28	increased films processed - Ran 10 fully exposed 14x17

Table 3.1. Contents of QC room logs

Room equipment survey (including overload protection factors for x-ray tubes)
Quality control procedures
Visual and manual quality control checks
Control charts for:
mR/mAs
Linearity
Repeatability
kVp
Timer accuracy
Half-value layer
Focal spot size
Collimator
Standard fluoroscopic exposure rate
Maximum fluoroscopic exposure rate
Phototiming
Phantom film entrance exposure and film density
Tomography
Maintenance logs
Miscellaneous
Polaroid photos of standard x-ray output waveforms
Star and/or pinhole focal spot images
Collimator test images

the department when you are considering the potential for new equipment. (It may also be worthwhile to indicate total downtime for the equipment since this may be considerable in cases where a service company may have difficulty in providing rapid response to your calls or may have difficulty in obtaining repair parts—the specific facts and times should be noted for future reference.)

The items listed under the "Miscellaneous" category provide important information. All of the standard images—x-ray output waveform, focal spot, tomographic phantom, and collimator test—are needed for reference in the future to determine if changes have occurred. However, don't become a collector and end up with piles of these images—the only ones that are valuable are the initial ones made on the equipment (which ideally should have been made when the equipment was installed) and the most recent images. These two sets of images should always be compared critically with the images from the present QC checks to assure that no significant changes have occurred. You may want to consider keeping copies of "interesting cases" in your office file for teaching purposes or to show to your colleagues when they ask what types of problems you are finding.

Like control charts, room logs are only as good as the data in them. Be sure to keep them up to date and assure that all necessary information is present. Most importantly, assure that anyone could go to the log, if necessary, and determine how the tests were carried out and equate the results.

PROCEDURES

3.1. CONTROL CHARTS

Purpose

To provide a graphical means of recording data for easy analysis and interpretation.

Equipment Needed

1. Graph paper or specialized control charts
2. Pencil and ruler

Procedure

1. All data collected *must* be plotted on control charts, including the actual data points, the date the data were collected, and the corrective action taken, if any.
2. The operating levels and control limits (both upper and lower control limits) must be determined and indicated on the control chart (see the sample control chart in Figure 3.2). If you are plotting the measured kVp, then the operating level becomes that level at which the control panel is set, e.g., 80 kVp.
3. The control limits are those levels that, if exceeded, require that corrective action be taken (e.g., a service engineer is called to calibrate the equipment). For example, we may wish to maintain our generators within ± 3 kVp, so the upper control limit becomes 83 kVp and the lower control limit is set at 77 kVp.
4. Sometimes it is not as easy to establish the operating level and control limits. For example, with photographic processors there are no absolute values you can use. These will have to be established in a manner similar to the operating levels and control limits described on pages 44–45.
5. As soon as you have plotted the data points you should immediately determine if any of the points lay outside of the control limits.
6. To assure that you did not make some mistake or that your data are not incorrect because of experimental error, it is wise, and probably time saving, to repeat any test that indicates that the process is out of control, especially if a data point lies on or just outside of the control limits.
7. If corrective action is required, repeat the test after the correction has been made. [***Note:*** This is especially important to do if you rely on service engineers who are not affiliated with your institution. Remember, as a QC technologist, you were delegated the duties by your radiologist and are responsible for the safety of your patient and for assuring that the radiographs you produce are of the best quality possible.]
8. Circle the data points for out-of-control results and then plot the in-control data points (obtained from postcorrection testing), connecting the latter points to the in-control data points from the previous QC test with straight lines.
9. Record the corrective action taken on the bottom of the control chart or on the maintenance record log, which should be part of your QC room log.
10. You may encounter a condition in which the data points are all within the control limits but in which the process is considered to be out of control. This occurs when a process exhibits trends or drift. A trend, or drift, is indicated when *at least three* data points move in either the upward or downward direction. This means that the process is not in control. If allowed to continue to operate in this manner, the data points will soon be outside of the control limits. Be sure to scrutinize your control charts for trends whenever you plot the data.
11. In addition to the possibility of control limits and trends becoming apparent, your control charts will exhibit normal random variation (see Figures 3.1 and 3.2). This type of variation is to be expected since it is due to the normal variation in the process and the experimental error in your measurements.

Problems and Pitfalls

1. The major problem associated with control charts is failing to keep them up to date with the pertinent measurement data, the date of the measurements, and the corrective action and corrected data points. A control chart only provides the history of your equipment or processes if you keep the history up to date.

2. An important pitfall is that many people do not recognize random variation in the data, which is inherent, and they expect the data to fall along the operating level at all times. The data will vary randomly around the operating level but should remain within the control limits, not exhibiting any trends.
3. There is a tendency to record data on various bits and pieces of paper or to develop a survey sheet for a room of x-ray equipment that contains all of the information about the room on a single date. The purpose of a control chart is to provide a working sheet that can be filled in while you are making the measurements. A control chart should be a single graph exhibiting all the measurements of a single parameter made at different times so you can visually scrutinize the changes that may be taking place in that single variable, rather than a single sheet containing all of the various measurements made on one day.
4. The major pitfall in using control charts is the reticence of the user to call for corrective action when the control chart so indicates, i.e., when the control limits are exceeded or trends are apparent. When the control limit is reached or exceeded, the test should be repeated. If the second set of data still indicates that the control limits have been met or exceeded, *corrective action is required immediately.* If trends are apparent over three or more data points, *corrective action is required immediately.* The purpose of control charts and a quality control program is to *control quality,* not to monitor quality or the lack of quality.

3.2. QUALITY CONTROL ROOM LOGS

Purpose

To provide a source of information concerning the operating conditions of equipment, equipment failures, preventive maintenance, or any other activity that may influence the quality of the end product.

Equipment Needed

1. Three-ring notebooks
2. Notebook dividers
3. Control charts, maintenance logs, etc. (see Appendix A)
4. Pencil and ruler

Procedure

1. Establish a complete QC room log for each room of x-ray equipment. This should include all of your control charts for that room, a set of instructions on how the measurements are made in that particular room (including kVp, mA, and exposure time settings), the source-to-image distance, and any settings peculiar to the room, plus a maintenance log. A complete survey of the equipment, including serial numbers and dates purchased, should be an integral part of the log.
2. It is the QC technologists' responsibility to see that the QC room logs are established and maintained. It is also their responsibility to enter the data on the control charts as the measurements are being made.
3. It is the responsibility of the service engineer to enter the appropriate information in the maintenance log, which is part of the QC room log, so that the technologist will know what adjustments or changes have been made to the equipment. This is particularly important if maintenance work is carried out during off hours.
4. The QC technologist should review the entire QC log every time he or she evaluates the room and every time any changes are made in the equipment. The QC technologist must make evaluations of any parameters that may be affected by changes carried out by the service engineers and enter the appropriate data in the control charts. In addition, all data that are not fully understood or are confusing must be reviewed with the radiologic physicist as soon as possible.

Problems and Pitfalls

1. The most prevalent problem is not entering *all* data in the QC room log as soon as it is collected. If it is first recorded on bits and pieces of paper, it will become confused and ultimately lost, thereby negating the efforts of the quality control technologist.
2. Not only must new data be entered but previous data must be reviewed to see if the new measurements are meaningful.