Compliance Guidance for RADIOGRAPHIC QUALITY CONTROL



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DEDICATION

This Guidance Document is dedicated to the memory of Joyce Zeisler. Her efforts to improve Quality Assurance Programs in New Jersey were instrumental in bringing about this program.

ACKNOWLEDGEMENTS

This Guidance Document was prepared through the efforts, advice and input of many people. We offer our thanks to all of the contributors. In particular, we thank the principal author: Catherine H. Clawson, Supervising Radiation Physicist.

DISCLAIMER

This Compliance Guidance Document is not a substitute for the Department's regulations and compliance is not required with the procedures in this document. The procedures and/or methods described in this document are provided for information only. Performing these procedures does not necessarily constitute Department approval or guarantee compliance.

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DEDICATION	
ACKNOWLEDGEMENTS	ii
DISCLAIMER	ii
INTRODUCTION	1
RADIOGRAPHIC QUALITY CONTROL	
Frequency	
Consistency is the Key!	
Competency	
Training Options	
Polaroid Instant Film System	
Using this Guidance Document	
Additional Documents Available	
Table 1 - Radiographic Quality Control Requirements	
Table 2 - Record Retention	
EQUIPMENT WARM-UP	
Procedure 1 - Equipment Warm-up	
PROCESSOR QUALITY CONTROL	
You must ensure that QC is performed on each processor	
Select an Appropriate Sensitometer	9
Select an Appropriate Densitometer	9
Select an Appropriate Thermometer	10
Obtain Control Film	
Check Densitometer Calibration Daily	
Process and Read Sensitometer Strips Promptly	
Use Control Charts	12
Establish Operating Levels and Control Limits	
Polaroid Instant Film System.	
Procedure 2A - Establish Processor Operating Levels and Control Limits	
Procedure 2B - Daily Processor Quality Control	
Figure 2 – Example of a Daily Processor Quality Control Sensitometric Strip	
Troubleshooting Guide to Processor Problems	
Procedure 2C - Control Film Crossover	
Manual Processing by the Time – Temperature Method	
LASER FILM PRINTER QUALITY CONTROL.	
Procedure 3A - Establishment of Laser Film Printer QC Operating Levels	
Procedure 3B - Weekly Laser Film Printer Quality Control	
DARKROOM CLEANLINESS	
Procedure 4 - Darkroom Cleanliness	
PROCESSOR MAINTENANCE AND CHEMICAL SOLUTIONS	
FACILITY'S EQUIPMENT VISUAL CHECKLIST	31
Procedure 6A - Equipment Visual Check List	
Procedure 6B - View Box Cleaning	
FILM & CHEMICAL SHELF LIFE.	
Procedure 7 - Film & Chemical Storage	
LIGHT FIELD/X-RAY FIELD ALIGNMENT.	
Procedure 8A - X-ray Field/Light Field Alignment	
Figure 8A - X-Ray Field/Light Field Alignment	
Figure 8B - X-Ray Field/Light Field Alignment Sample Evaluation Results	
REPEAT ANALYSIS.	

TABLE OF CONTENTS

Procedure 9 - Repeat Analysis	.39
ARTIFACT EVALUATION.	40
Procedure 10 - Artifact Evaluation	
Some Common Artifacts and Their Causes	.42
ANALYSIS OF FIXER RETENTION	.43
Procedure 11 - Analysis of Fixer Retention	
DARKROOM FOG.	
Procedure 12 - Darkroom Fog	
SCREEN-FILM CONTACT/CASSETTE INTEGRITY/SCREEN CLEANLINESS	
Procedure 13A - Film-Screen Contact	
Procedure 13B - Cassette Integrity	
Procedure 13C - Screen Cleanliness	
LEAD APRONS, GLOVES, GONADAL AND THYROID SHIELDING INTEGRITY CHECK	
Procedure 14 - Lead Shielding Integrity Check	
MEDICAL PHYSICIST'S RADIOGRAPHIC Q C SURVEY	
QUALITY ASSURANCE PROGRAM REVIEW.	
BIBLIOGRAPHY.	
EQUIPMENT NEEDED TO PERFORM QC TESTS	
VENDORS LIST	
Sensitometer and Densitometer Calibration Vendors	
Quality Assurance Supply Vendors	
OPTIONS For When The Facility's Sensitometer and/or Densitometer Is Unavailable	
NEXT DATA	
1994 PA Chest NEXT Data	
1995 Abdomen and LS Spine NEXT Data	.0/
2000-2001 NJ Foot ESE Data	
FORMS.	
Form 1 - Processor Quality Control Chart.	
Form 1A - Example of a Completed Processor Quality Control Chart	
Form 2 - Establishing Film Processor Operating Levels Worksheet	
Form 2A - Example of a Completed Establishing Film Processor Operating Levels Worksheet	
Form 3 - Cross-Over Data Sheet.	
Form 3A - Example of a Completed Cross-Over Data Sheet	
Form 4 - Laser Film Printer Quality Control Chart	
Form 4A – Example of a Completed Laser Film Printer Quality Control Chart	
Form 5 - Quality Control Log – Bimonthly Tests	
Form 6 - Quality Control Log – Semi-Annual Tests	
Form 7 - Quality Control Log – Annual Tests Part 1	
Form 8 - Quality Control Log – Annual Tests Part 2	
Form 9 - Facility's Equipment Visual Checklist	
Form 10 - Repeat Analysis Form	
Form 10A - Example of a Completed Repeat Analysis Form	
Form 11 - X-ray Field/Light Field Alignment	
Form 11A - Example of a Completed X-ray Field/Light Field Alignment Test	.86

INTRODUCTION

On January 16, 2001, the Department of Environmental Protection (Department) and the Commission on Radiation Protection adopted regulations (New Jersey Administrative Code 7:28-22) that require any facility performing diagnostic x-ray procedures (radiography, fluoroscopy, x-ray bone densitometry or computed tomography) to develop and continuously implement a Quality Assurance program. The regulations apply to equipment used on humans in hospital, medical, podiatric, chiropractic, industrial, school, and government facilities.

The requirements of N.J.A.C. 7:28-22 do NOT apply to mammography equipment that must comply with Federal Mammography Quality Standards Act, 42 U.S.C.A. §263(b) or N.J.A.C. 7:28-15.4.

A Quality Assurance (QA) program, which includes quality control tests, helps to ensure that high quality diagnostic images are consistently produced while minimizing radiation exposure. The QA program covers the entire x-ray system from machine, to processor, to view box. This program will enable the facility to recognize when parameters are out of limits, which could result in poor quality images and can increase the radiation exposure to patients. Simply performing the quality control tests is not sufficient. When quality control test results exceed established operating parameters, appropriate corrective action must be taken immediately and documented.

This guide is intended to assist the facility in setting up their QA Program and performing the quality control tests required to maintain high quality images and reduce patient exposure. This guide includes generally accepted procedures that the facility may use to perform the required tests. The procedures in this guide are not the only way to perform the tests. Alternative test procedures may be used without Department approval. However, all procedures being used must be documented in the facility's QA manual and meet the requirements of N.J.A.C. 7:28-22. In some cases, manufacturer's directions may be more appropriate than the generic procedures in this guide.

Product manufacturers, vendors, and service companies all have information available in the form of leaflets, videos and hands-on help. If the facility finds that they need more instruction than this guide provides, please use these companies and the medical physicist as resources. A bibliography that includes some of the available books on quality assurance is on page 54.

The responsibility for the quality control tests should be assigned to a QA program coordinator to ensure consistency in test methodology and interpretation of the data. More than one person may perform the tests but one person should assume overall responsibility for the day to day operation of the program. This leads to better understanding of when to repeat tests, call for service, or consult with the practitioner or medical physicist. The physician, medical physicist, and QC personnel, working together as a team, are the key to providing optimum quality radiographic images.

Due to the importance of quality control in diagnostic imaging, it is recommended that the appropriate facility personnel review the control tests, data and images quarterly.

Radiographic Quality Control

The regulation requires that each facility with radiographic equipment perform, or have performed, the tests in TABLE 1, "Radiographic Quality Control Requirements" (page 5), at least at the frequency specified, and maintain records of the test results.

FREQUENCY

The frequency of tests specified in TABLE 1 is the minimum frequency. The frequency of quality control tests may need to be increased depending on many factors including the age and stability of the x-ray equipment and film processing equipment, as well as the number of problems being encountered.

Tests may always be performed at a GREATER frequency than required by N.J.A.C. 7:28-22. Tests may NOT be performed at frequencies LESS than required in N.J.A.C. 7:28-22 unless approved by the Department as outlined in N.J.A.C. 7:28-22.3(f). For example, if the facility decides to check darkroom fog quarterly, this new frequency must be documented in the facility's QA manual and the test data needs to be recorded appropriately.

CONSISTENCY IS THE KEY!

After each link (x-ray unit, processor, film-screen combination, darkroom, etc.) in the imaging chain is optimized, a working QA program will provide warning flags to the QA program coordinator when something goes awry. If the coordinator finds, during the daily review, that the established tolerances are exceeded, **the test or tests must be repeated to verify the results, then corrective action must be taken.** The coordinator must be capable of identifying problems and willing to resolve them as they occur, or the QA program will not provide the intended benefits.

TRAINING

The registrant, per N.J.A.C. 7:28-22.5(d), must ensure that all individuals, performing any of the quality control tests, have an appropriate level of training to perform the tests competently. The regulations do not specify that a physician, a radiologic technologist or a physicist must perform the tests (The only exception is the Medical Physicist's QC Survey which must be performed by a Medical Physicist meeting the requirements of N.J.A.C. 7:28-22). Anyone with adequate training can perform quality control tests. The level of training required depends on the test being assigned. Some procedures such as darkroom cleaning require minimal training. Performing the Processor Quality Control requires more training. The facility must ensure that there are sufficient trained personnel so that there is always someone available (i.e. to cover vacation and sick time) to perform the necessary testing.

TRAINING OPTIONS

The registrant may train their own personnel. This assumes that the registrant is competent in the particular procedure and is able to convey this knowledge adequately to the personnel. Product manufacturers, vendors, and service companies have training aids available in the form of leaflets and videos. Companies whose sole purpose is training as well as service and repair companies and the facility's medical physicist can provide seminars and training courses ranging from a few hours to several days or more on the how to of Quality Control tests. Adequate training of personnel will ensure that the tests are performed correctly and consistently.

USING THIS GUIDANCE DOCUMENT

<u>This document is intended to provide guidance for performing QC tests for radiographic</u> <u>machines only.</u> Additional compliance guidance documents are available for the QA Manual, Fluoroscopy QC tests and CT QC tests. See the section entitled, "Additional Documents Available" for information on receiving these documents. Several other documents are listed in the last section that the facility might find useful.

A detailed description of each required test follows in the order listed in TABLE 1. This is the same table that appears in the regulation at N.J.A.C. 7:28-22.5.

Records of Quality Control test results, corrective actions, Medical Physicist's QC Survey, and Quality Assurance Program Review must be maintained for at least the time period specified in TABLE 2 (page 6).

Sample forms can be found in the FORMS section beginning on page 69 of this document. Forms provided here may be modified to meet facility needs provided that sufficient information is included to demonstrate compliance.

A list of equipment needed to carry out the QC tests can be found in the EQUIPMENT section beginning on page 57.

A list of vendors of QC equipment can be found in the VENDOR section beginning on page 59.

POLAROID INSTANT FILM SYSTEM

The Polaroid Co. offers an instant film system (8X10 film for extremity use only) that operates without a dark room, without the standard processor, and without separate processing chemicals. Accordingly, Test Items 2, 4, 11, and 12 in Table 1 are not applicable. Specific guidance for users of the Polaroid system is included on pages 13 and 30.

ADDITIONAL DOCUMENTS AVAILABLE

Compliance Guidance for QA Manual: this document provides guidance in setting up a QA program, assignment of QC testing to various individuals, and the information required to be maintained at the facility.

Compliance Guidance for Fluoroscopic Quality Control: this document contains detailed descriptions for performing the QC tests required for fluoroscopic machines.

Compliance Guidance for Computed Tomography Quality Control: this document contains detailed descriptions for performing the QC tests required for computed tomography machines.

Radiation Safety Manual: this document provides guidance to setting up the radiation safety manual as required by N.J.A.C. 7:28-15.9(a) 8.

List of Qualified Medical Physicists for QC Surveys: certain tests must be performed by or under the direction of a medical physicist meeting certain educational and experience requirements. This document contains a current list of individuals who meet the requirements of N.J.A.C. 7:29-22.

List of Qualified Individuals for the Performance Of Radiation Safety Surveys of the Environs: this document contains the names of individuals who meet the educational and experience requirements in N.J.A.C. 7:28 to perform radiation safety surveys of the environs on x-ray equipment. The individuals on this list are not necessarily the same individuals as on the qualified medical physicists for QC surveys list.

Commercial Personnel Monitoring Services: this document contains the names of companies that provide radiation monitoring equipment (badges).

Assemblers list: this document contains a list of vendors who sell and repair x-ray equipment.

NOTE: List of vendors for QC equipment is in this document in the Vendor section on page 59.

Copies of these documents can be obtained from the Department by any of the following methods. If faxing or mailing a request, please be sure to include your name and mailing address or fax number. Due to the length of the compliance guidance documents, we are not able to fax them, however they may be downloaded from our web site.

Internet Web site: <u>http://www.state.nj.us/dep/rpp</u>

Fax request to: 609-984-5811

Mail request to:New Jersey Department of Environmental Protection
Bureau of Radiological Health
PO Box 415 Trenton, NJ 08625

TABLE 1 Radiographic Quality Control Requirements To be performed by appropriately trained personnel				
ltem	Required Test or Procedure	Frequency	Standard	
1	Equipment Warm-up Procedure	Daily or each day x-rays are taken	Warm up tube; ensure equipment is working properly	
2	Processor Quality Control (Sensitometry/Densitometry)	Daily or each day x-rays are taken	Medium Density ∀0.15 Optical Density (OD) Density Difference ∀0.15 OD Base+Fog +0.03 OD of operating levels	
3	Laser Film Printer Quality Control	Weekly	SMPTE Test PatternInverted gray scale0% patch $2.45 \forall$ 0.15 OD0% patch $2.50 + 0.15$ OD10% patch $2.10 \forall$ 0.15 OD10% patch $2.25 \forall$ 0.15 OD40% patch $1.15 \forall$ 0.15 OD40% patch $1.35 \forall$ 0.15 OD90% patch 0.30 \forall 0.08 OD90% patch 0.30 \forall 0.08 ODThe 5% patch should just be visible inside of the 0% patch.The 95% patch should be visible inside the 100% patch.	
4	Darkroom Cleanliness	Weekly	Free from dust and dirt	
5	Processor Maintenance and Chemical Solutions	Initially and every 2 months (more frequently if needed)	Manufacturers' specifications	
6	Facility's Equipment Visual Checklist	Initially and quarterly	All tests passed	
7	Film and Chemical Shelf Life	Initially and quarterly	Use film and chemicals with earliest expiration date first	
8	Light Field/X-ray Field Alignment	Initially, quarterly and after service	Not to exceed 2% of Source to Image Distance (SID)	
9	Repeat Analysis	Semiannually (review rejected films immediately for corrective action)	No standard, but goal should be <5%	
10	Artifact Evaluation	Examine every film for artifacts, in-depth evaluation semiannually	No significant artifacts	
11	Analysis of Fixer Retention	Initially and semiannually	# 5 micrograms/sq. centimeter or # 0.05 grams/sq. meter	
12	Darkroom Fog	Initially, semiannually and after service	#0.05 Optical Density Difference	
13	Screen-Film Contact/Cassette Integrity/Screen Cleanliness	Initially and annually or as needed	No areas of poor contact > 2cm. in diameter	
14	Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	Initially and annually	No breaks in protective garments	
15	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.8	
16	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7	

TABLE 2 Record Retention		
Record Type	Minimum Retention Time	
Documentation of EACH corrective action, repair and service	Two Years	
Test Results for items 2, 3, 5, 6, 8, 9, 10, 11, 12, 13, & 14 in TABLE 1, Radiographic Quality Control Requirements	One Year	
Radiation Safety Survey of the Environs	As long as machine is owned plus one year	
INITIAL Medical Physicist's QC Survey report	Permanently	
ANNUAL Medical Physicist's QC Survey report	Two Years	
Quality Assurance Program Review report	Two Years	

Equipment Warm-up

<u>Test Frequency - Each day of operation</u> Standard - Ensure equipment is working properly.

Each day during the x-ray generator warm-up, and before exposing the first patient to x-rays, check for indicator (kVp, x-ray on light or audible signal etc.) malfunction and the mechanical and electrical safety of the x-ray system. Malfunctions and unsafe conditions (such as frayed wires) must be corrected promptly.

Follow the x-ray system manufacturer's recommended warm up procedure. If no manufacturer's procedure is available, use Procedure 1 below.

Procedure 1 Equipment Warm-Up

- 1. Turn on system.
- 2. Set the machine parameters as follows:
 - i. 50- 60 kVp
 - ii. Set timer to 1 second
 - iii. Large Focal Spot
 - iv. Lowest mA possible for Large Focal Spot
 - v. Standing in a shielded area, make 4 exposures waiting 30 second between exposures.

NOTE: If the tube is idle for more than 2 hours another warm up should be performed.

CORRECTIVE ACTION: If an unusual noise, sparking or other event is noted, equipment should not be used until repairs are completed. Contact a x-ray service company for repair. All corrective actions must be documented and the records retained for a minimum of 2 years.

Records: No records are required to be maintained of this procedure.

Processor Quality Control

Test Frequency - Each day before x-rays are takenStandard -Medium Density ∀0.15 Optical Density (OD)Density Difference ∀0.15 ODBase + Fog +0.03 OD of operating levels

On each day of operation, the processing system must operate as close as possible to the film manufacturer's temperature and speed recommendations. Processor Quality Control is important to verify that the film processor and the chemical system work in a consistent manner. It is very important that corrective action be implemented when the limits are exceeded or a pattern develops indicating a degradation of the system. Facilities that use film types of different speeds should use their most sensitive type film for processor QC.

You must ensure that QC is performed on EACH processor

The NJ regulation specifies that processor QC MUST be performed every day that patient x-rays are taken and before patient films are processed.

Each processor in the facility must be tested. Having one processor in control does not ensure that all other processors in the facility are in control.

If a facility has one processor and performs both mammography and diagnostic imaging, the mammography film should be used for processor QC, as it is usually the more sensitive film. If the facility uses the mammography film for processor QC testing, the facility must be sure to use the mammography film for processor QC on all days even if mammography is not being performed every day.

Processor QC must be performed EACH day on EACH processor before any patient films are taken. This includes weekends and holidays. QC must be performed on processors used in hospital emergency departments or mounted in mobile vans.

The facility must ensure that if the sensitometer and/or densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the processor is operating within control limits before patient x-rays are taken. There is a list of options the facility may consider for meeting this requirement on page 62.

Before you begin your processor quality assurance program, you must:

Select an Appropriate Sensitometer

A sensitometer is a device containing a light source and a timing mechanism designed to give precise, repeatable and graduated light exposures to the radiographic film. The sensitometer is used to expose radiographic film to produce sensitometric control strips. These control strips are then processed to provide information that evaluates processor operation.

It is important that the light emitted by the sensitometer "matches" the film used by the facility. In other words, if the facility uses blue light sensitive film and intensifying screens, the sensitometer must emit blue light. Most sensitometers have a switch that allows the user to choose blue or green. The facility must ensure that the sensitometer is set to the appropriate color for their film.

If using dual-emulsion film, the sensitometer should expose both sides of the film simultaneously. However, the Bureau of Radiological Health has determined that acceptable results are obtained using a single sided sensitometer with dual emulsion film.

If using dual-emulsion film with different emulsion types on each side (such as Kodak Insight film), you must be sure to always expose the same emulsion side of the film. The film has a notch on one or more sides to indicate the different emulsion sides. Ensure that the film is always inserted into the sensitometer with the same side down.

This document assumes that the facility is using a sensitometer that produces 21 optical density steps. If the facility is using a sensitometer with a different number of optical density steps, they will need to adjust the procedures and forms accordingly.

If the sensitometer needs to be calibrated, it must be returned to its manufacturer or another vendor. A list of vendors who calibrate sensitometer and densitometers is on page 60.

The facility must ensure that if the sensitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the processor is operating within control limits before patient x-rays are taken. There is a list of options the facility may consider for meeting this requirement on page 62.

Select an Appropriate Densitometer

A densitometer is a device that measures the optical density of a developed radiographic film such as the sensitometric control strips. Evaluation of the processor operation requires that the sensitometric control strips be processed, the densities measured with the densitometer, and these measurements compared to a standard or past values. The sensitometric control strips must be read with a densitometer. It is inappropriate to visually compare sensitometric control strips. The densitometer should provide sufficient range to properly read the sensitometric control strips produced.

If the densitometer needs to be calibrated, it must be returned to its manufacturer or another vendor. A list of vendors who calibrate sensitometer and densitometers is on page 60.

The facility must ensure that if the densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the processor is operating within control limits before patient x-rays are taken. There is a list of options the facility may consider for meeting this requirement on page 62.

Select an Appropriate Thermometer

For monitoring the temperature of the film processor, it is recommended that only a digital thermometer be used. Avoid the use of a glass thermometer as they are easily broken in the processor. *NEVER* use a thermometer that contains mercury since the mercury is a photographic contaminant. The thermometer used for monitoring the developer temperature must be accurate to at least $\forall 0.5$ EF. A clinical digital fever thermometer can be used.

Remember that the temperature of the processor solutions is critical to proper film development. Accurate and timely temperature measurements are essential to the QA program.

Obtain Control Film

A box of radiographic film should be reserved and used for QC testing only. The box should be clearly marked "FOR QC TESTING ONLY". If more than one type of film is used in the facility, the most sensitive film should be used for the processor quality control.

The control film need not be the same size as the clinical film. In other words, the QC film can be 8 X 10 even if all clinical images are produced on 14 X 17 film. The film, however, must be of the identical type as the clinical image film.

It is recommended that all facilities dedicate a box of film for QC testing. However, facilities with very small volume may use film from the clinical batch for QC testing also. If a facility chooses to do this, <u>it is necessary to remember to leave sufficient film (five sheets)</u> in the batch to perform crossover (Procedure 2C Control Film Crossover) when new film of a different emulsion batch number is purchased. Facilities, who do not dedicate a box of film for QC testing, may have to perform crossover more often then facilities that dedicate a box of film to QC testing.

The facility must plan ahead. If there are not five sheets of the old QC film available to perform a cross-over, it will be necessary to re-establish the operating limits (Procedure 2A Establish Processor Operating Levels and Control Limits) for the new QC film.

To obtain the best results, you must:

Check Densitometer Calibration Daily

The calibration of the densitometer should be checked daily before use to ensure that it is functioning properly. The densitometer manufacturer supplies a calibrated step tablet when the unit was purchased. Carefully follow the manufacturer's instructions for using this calibration tablet to verify that the densitometer is still calibrated over the range specified.

If the calibration tablet check indicates that the densitometer is out of calibration, most densitometers have a screw adjustment that can be used for making minor changes. Follow the manufacturer's instructions for performing this adjustment. If the densitometer cannot be brought into calibration by facility adjustment, the densitometer must be returned to the manufacturer for a more thorough calibration or repair.

If the densitometer needs to be calibrated or repaired, it must be returned to its manufacturer or another vendor. A list of vendors who calibrate sensitometer and densitometers is on page 60.

The facility must ensure that if the densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the processor is operating within control limits before patient x-rays are taken. There is a list of options the facility may consider for meeting this requirement on page 62.

When reading any step on the strip, the density should be measured in the center of the step. The values given for the strip and those taken daily should agree within the manufacturer's specifications (usually $\forall 0.02$ or $\forall 0.03$) for all steps of the strip.

For the daily Processor QC care must be taken to correctly identify the steps to read. The same steps must be read each time.

Process and Read Sensitometric Control Strips Promptly

It is essential that the sensitometric control strip is exposed, immediately processed, read with a densitometer, and the data plotted to determine whether the processor is operating properly *before* processing any diagnostic radiographs.

Sensitometric strips that are pre-exposed (hours or days in advance) will suffer from latent image effect and will not be as sensitive as freshly exposed strips to changes in the processor function. Diagnostic images are not to be processed until the processor is determined to be operating

within manufacturer's specifications. It is inappropriate, and illegal, to process clinical films and then determine, hours or days later, that the film processor was not operating optimally.

Use Control Charts

Control charts are needed to plot and review acquired data. Whenever a data point reaches or exceeds the control limits, the test should be repeated immediately. If the repeated measurement still reaches or exceeds the control limits, then <u>immediate corrective action is required</u>. The out-of-control data point should be circled, the cause of the problem noted, corrective action performed, documented, and then retested and the in-control data point plotted.

The initials of the individual who performed the sensitometric evaluation of the processor and the date the test was performed should be indicated. Notes regarding changes in operating conditions (such as a change in the developer temperature or replenishment rate) should be recorded on the control chart.

The control chart is also useful in detecting trends that indicate an unstable process. A trend is an upward or downward change in the measured data when three data points move in the same direction. The cause of trends should be investigated before the control limits are reached or exceeded.

Establish Operating Levels and Control Limits

When establishing a processor quality control program, it is necessary to determine the operating levels and control limits. The operating level is the level normally expected. The control limits are the extreme ranges of acceptable operation. If the daily test shows that the control limits are exceeded, the quality control test should be repeated. If the result is still out of limits, corrective action must be taken **before** films are processed. Corrective actions may include changing the temperature of developer, replacing chemistry, etc. Assistance in diagnosing and correcting problems can be found in the numerous books on film processing, the facility's processor service company, film company representative and medical physicist.

DO NOT widen the control limits since the data indicates that the processor is out of control and corrective action is essential. These limits are set by NJ State regulation. Procedure 2A (Establish Operating Levels and Control Limits) must be performed when the quality control program is initiated or if there are not five sheets of the old QC film available to perform a cross-over, it will be necessary to re-establish the operating limits (Procedure 2A Establish Processor Operating Levels and Control Limits).

New Jersey Administrative Code 7:28-22.5 requires Processor QC on all processors. For Daylight systems, Rapido systems, or other "non-standard" processing systems it will be necessary for you to feed the sensitometric film through by the manual method. Please contact the equipment manufacturer, processor service company, imaging consultant or medical physicist for the best method of accomplishing this. If there is no way to manually feed the film

through the processor, consult with the above mentioned sources to determine the best way to comply with the processor QC requirements.

Polaroid Instant Film System

The Polaroid Corporation offers an instant 8 x 10 radiographic film system. The film size is limited to 8 x 10 which makes the system applicable to extremity radiography only. The system operates without a darkroom, without the standard processor and without separate processing chemicals. The film, after being exposed through the usual radiographic procedures, is processed using chemicals that are part of the film pack. Persons using the Polaroid system do not have to perform daily Processor Quality Control (Item 2, Table 1), Darkroom Cleanliness (Item 4, Table 1), Analysis of Fixer Retention (Item 11, Table 1), or Darkroom Fog (Item 12, Table 1). Processor Maintenance requirement (Item 5, Table 1) is limited to following the manufacturer's recommendation.

Procedure 2A Establish Processor Operating Levels and Control Limits

Equipment Required:

Sensitometer Densitometer Fresh box of control film. Form 1 Processor Quality Control Chart (page 70) Form 2 Establishing Film Processor Operating Levels worksheet (page 72) Digital thermometer accurate to at least $\forall 0.5^{\circ}F$

Sensitometry Control Limits

Medium Density (MD) \forall 0.15 Optical Density (OD) Density Difference (DD) \forall 0.15 Optical Density (OD) Base + Fog: within 0.03 OD of established operating levels **NOTE:** MD and DD values that exceed ± 0.10 should be investigated immediately before limit of ± 0.15 OD is exceeded.

- 1. Prior to establishing processor operating levels and control limits, the processor must be cleaned and filled with fresh chemistry.
 - **a.** For automatic film processors, chemistry, replenishment rates, developer, fixer, and water temperatures and film transport timing mechanism must be within the film and processor manufacturers' specifications.
 - b. For manual film processing, chemistry must be within film manufacturer's specifications. All films must be processed using the time-temperature method per N.J.A.C. 7:28-22.5(c). Sight processing is prohibited. A procedure for Manual Processing by the Time-Temperature Method can be found on page 24.
- 2. Turn on processor and allow to warm up per manufacturer's recommendations.
- 3. Run a sheet of clear film through the processor. This will help clean the rollers of debris.
- 4. Determine the temperature of the developer. Record on the Processor Quality Control chart (Form 1).
 - a. For automatic film processors, the temperature must be within the processor and film manufacturers' specifications (usually +/- 0.5 degrees F.).
 - b. For manual film processing, this temperature will be used to determine the accurate length of processing time. Refer to the film and chemical manufacturer's time-temperature chart. Chemistry should be mixed well before use. Tanks should be covered when not in use to prevent evaporation and oxidation of solutions.
- 5. Turn on sensitometer and follow manufacturer's instructions for warm up. Ensure glass surface of sensitometer is clean. If necessary clean with a small amount of glass cleaner and allow to dry before using. Be sure sensitometer is set to the proper light, blue or green, to match the film being used
- 6. Process one sensitometric strip each day for five consecutive days. After five days you will have five sensitometric control strips.
 - a. Place a sheet of film from the QC box in the sensitometer and activate the sensitometer by pressing down once. For single-sided emulsion film, the emulsion side of the film must be placed down in the sensitometer. The emulsion side can be

detected in reflected safelight by locating the shinier side or by locating the notch on the edge of the film. Refer to the film box for the notch position to determine the emulsion side.

- b. Process film immediately.
- c. For automatic film processors, all films must be fed into the processor on the same side of processor tray.
- d. For single-sided emulsion film, it is important to process the film consistently with the emulsion side is either always side up or always side down as it is fed into the processor.
- 7. After you have five sensitometric control strips produced over five days:
 - a. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. Follow manufacturer's procedure to adjust the calibration of the densitometer if necessary. If the calibration can not be brought into specifications by this adjustment, the densitometer must be returned to the manufacturer (or other vendor) for re-calibration. See page 62 for a list of options for when the densitometer is unavailable.
 - b. With the densitometer, read the density of each of the 21 steps for all five sensitometric control strips. If the densitometer has several aperture sizes, use the 2mm aperture. Density reading should be taken in the center of the step. Record the data on Form 2 Establishing Film Processor Operating Levels worksheet.
 - c. Using the densitometer, determine the Base + Fog for all five sensitometric control strips. Base + Fog readings can be taken over any unexposed area of the film. Record the data on Form 2 Establishing Film Processor Operating Levels worksheet.
 - d. Determine the average density for each step by adding the five readings for that step and dividing by five. Record the data on Form 2 Establishing Film Processor Operating Levels worksheet.
 - e. Determine the average density for the Base + Fog by adding the five readings for the Base + Fog and dividing by five. Record the data on Form 2 Establishing Film Processor Operating Levels worksheet.
- 8. Using the density averages in 7. above, identify:
 - <u>a.</u> The Mid-Density (MD) step is the step where the average density is <u>closest to but not</u> <u>less than 1.20.</u>
 - b. The High Density (HD) step is the step where the average density is closest to 2.20.
 - c. The Low Density (LD) step is the step where the density is closest to but not less than 0.45.
 - d. Determine the Density Difference (DD) by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
 - e. Record on Form 2 Establishing Film Processor Operating Levels worksheet

- 9. On a Processor Quality Control Chart (Form 1) record:
 - a. The facility name, processor ID, if applicable, film brand name, emulsion number from the QC box of film, and date (month and year).
 - b. The MD average density value and the corresponding step number in the MD section of the chart.
 - c. The DD density value in the DD section of the chart.
 - d. The Base + Fog density value in the Base plus Fog section of the chart.
- 10. To determine the Control Limits
 - a. Add and subtract 0.15 Optical Density (OD) to the MD average density. Example: MD = 1.28; control limits = 1.43 and 1.13
 - b. Add and subtract 0.15 OD to the DD value.
 - Example: DD = 2.05; control limits = 2.20 and 1.90
 - c. Add and subtract 0.03 OD to the average Base plus Fog density. Example: B+F = 0.18; control limits = 0.21 and 0.15
 - d. Record these density values on the Processor Quality Control Chart (Form 1) at the appropriate places.
- 11. Re-establishing operating levels and control limits (step 1 8 above) is necessary if there is:
 - a. A change in film brand or speed
 - b. A change in the brand or type of chemistry
 - c. A change in the film manufacturer's specifications
 - d. A change in replenishment rate
 - e. A change in sensitometer or densitometer (such as calibration by manufacturer or using a different set)
 - f. A change in film processor
 - g. An insufficient number of films remain in the QC box to perform a crossover to a new QC box of film
 - h. A recommendation from the film manufacturer to re-establish the operating level. For example, Kodak suggests annual reestablishment.
 - i. A change in the volume of film processed

NOTE: Changing the chemistry, as part of routine preventative processor maintenance is not justification for re-establishing processor operating levels. Re-establishment of operating levels and control limits should never be done for the purpose of bringing an out of control processor into compliance. The reason why a processor is out of control must be determined and the problem corrected. Consult with your processor service company, imaging consultant or medical physicist for help if necessary.

An example of a completed Establishing Film Processor Operating Levels Worksheet can be found in the FORMS section as Form 2A (page 73).

Procedure 2B Daily Processor Quality Control

The regulations require that processor quality control be performed each workday when radiographs are to be processed, before processing any patient films but after the processor warm-up.

Equipment Required: Sensitometer

Densitometer Fresh Box of control film. Form 1 Processor Quality Control Chart (page 70) Digital thermometer accurate to at least $\forall 0.5^{\circ}F$

Sensitometry Control Limits

Medium Density (MD) \forall 0.15 Optical Density (OD) Density Difference (DD) \forall 0.15 Optical Density (OD) Base + Fog within 0.03 OD of established operating levels **NOTE:** MD and DD values that exceed ± 0.10 should be investigated immediately before the limit of 0.15 OD is exceeded.

- 1. Turn on processor and allow to warm up per manufacturer's recommendations.
- 2. Run a sheet of clear film through the processor. This will help clean the rollers of debris.
- 3. Check developer temperature.
- 4. For automatic film processors, the temperature must be within the film manufacturer's specifications (usually +/- 0.5 degrees F.). If out of manufacturer's specifications, adjust. Allow time for the temperature to stabilize before continuing. Check temperature again.
- 5. For manual film processing, this temperature will be used to determine the accurate length of processing time. Refer to the film and chemical manufacturer's time-temperature chart. Chemistry should be mixed well before use. Tanks should be covered when not in use to prevent evaporation and oxidation of solutions.
- 6. Turn on sensitometer and follow manufacturer's instructions for warm up. Ensure glass surface of sensitometer is clean. If necessary clean with a small amount of glass cleaner and allow drying before using. Be sure sensitometer is set to the proper light, blue or green, to match the film being used.
- 7. Before processing clinical images, use the sensitometer to expose and immediately process a sensitometric control strip. Place a sheet of film from the QC box in the sensitometer and activate the sensitometer by pressing down once. For single-sided emulsion film, the emulsion side of the film must be placed down in the sensitometer. The emulsion side can be detected in reflected safelight by locating the shinier side or by locating the notch on the edge of the film. Refer to the film box for the notch position to determine the emulsion side.
- 8. After processing, write date on film with permanent marker.
- 9. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by

using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.

- 10. Read the densities of the three steps established in Procedure 2A (Establish Processor Operating Levels and Control Limits) for MD, HD and LD and the Base + Fog. Write the densities on the film with permanent marker. See Figure 2 (Example of a Daily Processor Quality Control Sensitometric Strip) page 19.
- 11. Determine the Density Difference (DD) by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
- 12. Plot the MD, DD, and the base + fog on Processor Quality Control Chart (Form 1).
- 13. Determine if any of the data points exceed the control limits.
- 14. Circle the out-of-control data point, correct the cause of the problem and repeat the test, note the cause of the problem in the "Remarks" section of the control chart, and plot the in-control point.
- 15. Determine if there are any trends, (i.e. three or more data points moving in one direction [either upward or downward], in the MD, DD, or B+F). If trends are present but the data points have not, as yet, exceeded the control limits diagnostic images may be processed. However, it will be necessary to determine the cause of the trend and to monitor the processor daily to ensure that the control limits are not exceeded.
- 16. Actual sensitometric strips should be maintained for at least the current 6 weeks. The strips can be referenced if it is necessary to consult with a specialist on a processor problem.
- 17. Maintain Processor Quality Control Charts for at least one year.

CORRECTIVE ACTIONS: immediate action must be taken to correct any problems. Films must not be processed until processor is operating within limits set by the regulations. All corrective actions must be completed before patient films are taken, documented and records retained for a minimum of 2 years.

If the processor seldom has problems, DO NOT discontinue the quality control program. The lack of problems indicates that the process is in control at the present time but does not predict the stability of the processor in the future.

An example of a completed **Processor Quality Control** chart can be found in the FORMS section as Form 1A (page 71).

A Troubleshooting Chart with common processor indicator deviations and their possible causes can be found on page 20.

Records: The Processor Quality Control Chart (Form 1) must be maintained for 1 year, sensitometric strips (film) should be maintained for at least 6 weeks. Records of corrective actions must be kept for 2 years.

Figure 2 Example of a Daily Processor Quality Control Sensitometric Strip

The following image is a typical sensitometric strip shown here for reference. The optical densities and step numbers that a facility establishes in Procedure 2A (Establish Processor Operating Levels and Control Limits) for MD, HD and LD and the Base + Fog will probably not be the same as in the example. This figure represents the results of step 10 in Procedure 2B (Daily Processor Quality Control).

5/31/00 ettica 0.21 (B+F) - 0.47 (LD) - 1.85 (MD) 2.41 (HD) 2.41 TIME: DATE: IDNO 1.94 (DD)

Troubleshooting Guide to Processor Problems

This list is not intended to be all-inclusive. There may be other reasons for your particular processor deviations. If in doubt, please contact your processor service company, imaging consultant or medical physicist.

Indicator Deviation	Appearance on Film	Possible Causes
Increased mid-density	Increased overall density	Wrong control film Increased immersion time High Developer Temperature Fogged control film Over replenishment Unseasoned developer Contaminated developer Improperly mixed developer Fixer depleted Circulation problem Improper safelight/storage
Decreased mid-density	Decrease overall density	Decreased immersion time Low developer temperature Wrong control film Under replenishment Contaminated developer Improperly mixed developer Diluted developer
Increased density difference	Higher contrast Higher density areas darker than normal	Decreased immersion time Low developer temperature Under replenishment Unseasoned developer Contaminated developer Improperly mixed developer
Decreased density difference	Lower contrast Higher densities in lighter areas and lighter densities in higher density areas	Increased immersion time High Developer Temperature Over replenishment Contaminated developer Improperly mixed developer Depleted developer Improper safelight/storage
Increased mid-density and Decreased density difference	Density too high Contrast too high	Increased immersion time High developer temperature Over replenishment Contaminated developer

Troubleshooting Guide to Processor Problems (continued)

Indicator Deviation	Appearance on Film	Possible Causes
Decreased mid density and Increased density difference	Density low High contrast	Decreased immersion time Low developer temperature Under replenishment
Increased Base + Fog	Overall increase in density	Fogged film Wrong control film Increased immersion time High developer temperature Over replenishment Contaminated developer Unseasoned developer
Decreased Base + Fog	Overall decrease in density	Wrong control film Low developer temperature

Adapted with permission from a guide developed by Terry Konn, Program Director Radiologic Technology, Brookdale Community College

Procedure 2C Control Film Crossover

Radiographic film is manufactured in batches. Consequently, there may be slight variations in the film characteristics between batches. In addition, film aging and storage conditions can affect the sensitometric characteristics of the film. This means that the MD, HD, LD and DD values may not be the same between the two batches of film. Changes in these density levels may cause the processor to appear to be operating out of tolerances when it is not. When the number of films in the QC box is low and another box with the same emulsion batch number is not available, a crossover to a new box of film is needed. <u>Crossover is performed when the emulsion batch number of the QC film (not the clinical film) changes.</u>

NOTE: Facilities using the same box of film for both QC testing and clinical imaging (and another box of the same emulsion number is not available) **must** perform crossover procedure while 5 sheets of film remain. Crossover must be performed each time QC film with a different emulsion batch number is purchased.

NOTE: The facility must plan ahead. If there are not five sheets of the old QC film available to perform a cross-over, it will be necessary to re-establish the operating limits (Procedure 2A Establish Processor Operating Levels and Control Limits).

Equipment Required: Sensitometer

Densitometer Five sheets of film from old control film Fresh Box of control film. Form 1 Processor Quality Control Chart (page 70) Form 3 Crossover Data Sheet (page 74) Digital thermometer accurate to at least $\forall 0.5^{\circ}F$

- 1. While you have at least five sheets of the old QC film remaining, select a new box of QC film and label it for QC purposes only.
- 2. The chemicals in the processor should be seasoned. A crossover procedure cannot be performed immediately after routine preventative processor maintenance. Ensure that the processor is operating within the ± 0.10 control limits.
- 3. Turn on sensitometer and follow manufacturer's instructions for warm up. Ensure glass surface of sensitometer is clean. If necessary clean with a small amount of glass cleaner and allow drying before using. Be sure sensitometer is set to the proper light, blue or green, to match the film being used.
- 4. At the same time that processor QC is normally performed expose and immediately process five sensitometric control strips from the old box of QC film and five sensitometric control strips from the new QC box of film alternating between the two emulsion batches. You should cut a small corner off of the sheets from the new box so that you differentiate between the old and new sheets. When completed you will have 10 sensitometric strips.
- 5. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the

optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.

- 6. For the five strips from the old emulsion batch read the densities of the steps established in Procedure 2A, Establish Operating Levels and Control Limits, for MD, HD and LD and the base + fog. You should write the densities and the date on the film with permanent marker.
- 7. Determine the Density Difference (DD) of the old QC film by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
- 8. Record these values on the Crossover Data Sheet (Form 3) under Old Emulsion Data.
- 9. For the five strips from the new emulsion batch read the densities of the steps established in Procedure 2A, Establish Operating Levels and Control Limits, for MD, HD and LD and the base + fog. You should write the densities and the date on the film with permanent marker.
- 10. Determine the Density Difference (DD) of the new QC film by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
- 11. Record these values on the Crossover Data Sheet (Form 3) under New Emulsion Data.
- 12. Determine the difference in the MD, DD, and Base plus Fog between the new and old strips (i.e., new value old value). If the value of the new strip is higher than the old, the difference will be a positive number. If the value of the new strip is lower than the old, the difference will be a negative number.
- 13. Using the numbers obtained in 10, adjust the old operating levels for MD, DD, and Base plus Fog. This is accomplished by adding the old operating level to the difference obtained in 10.
- 14. Record the new operating levels, control limits and new emulsion batch number on a **new Processor QC Chart** (Form 1). In the "Remarks" section indicate that crossover was performed and the date.
- 15. The old Processor QC Chart is no longer used for daily processor QC data recording but must be maintained for at least one year.
- 16. If the new box of QC film produces densities such that the previously established steps for MD, HD and LD are no longer the best choices, then new steps must be established using Procedure 2A Establish Processor Operating Levels and Control Limits.

An example of a completed **Crossover Data Sheet** chart can be found in the FORMS section as Form 3A (page 75)

Manual Processing by the Time – Temperature Method

NJ regulation [N.J.A.C. 7:28-22.5(c)] requires that manual processing be performed using the time and temperature method. Manual developing by sight is not permitted because it decreases image quality. The film is not completely developed and exposure to enough light to "see" the image before the film is fixed may cause film fogging and a loss of contrast.

Between developing sessions keep covers on tanks to decrease evaporation and oxidation of chemicals.

Use type of chemistry recommended by film manufacturer. If the film manufacturer's time and temperature procedure for manual developing differs from the steps listed below, use manufacturer's procedure.

Procedure 2D Manual Processing

Equipment Required:

Manual tanks Film holder(s) Protective apron and gloves Thermometer Timer

- 1. Remove covers from tanks. Rubber apron and gloves should be worn to prevent contact with chemicals and protect clothing.
- 2. Check fluid level in tanks. If low, add chemistry.
- 3. Stir chemistry well.
- 4. Measure temperature of developer. If temperature is below 64°, increase developer temperature using tank manufacturer's recommended method. Allow time for developer temperature to increase before developing films. Check temperature again before starting procedure.
- 5. Depending on temperature of developer, film should be left in developer solution as follows:
 - a. Developer is $64^\circ 66^\circ = 7$ minutes
 - b. Developer is $68^{\circ} 70^{\circ} = 5$ minutes. Optimal for most films.
 - c. Developer is 72° $76^{\circ} = 4$ minutes
- 6. All of the following steps except for drying should be performed in the darkroom under safelights only. Ensure that the safelight used meets film manufacturer's specifications.
- 7. In the darkroom, remove film from cassette and attach to film hanger.
- 8. Immerse film completely in developer. Agitate film gently for the entire development time. Agitation will ensure that all parts of the film are developed to the same extent and ensure that air bubbles do not stay on the film and cause artifacts. Use a timer to ensure accurate timing.

- 9. When the required development time is completed, carefully remove film from developer tank and allow excess developer to drain off. Film should be drained over the developer tank or wash tank. Care must be taken not to drain developer into fixer tank.
- 10. Immerse film in stop bath or wash tank for at least 30 seconds. Drain well over wash tank.
- 11. Immerse film in fixer tank for 5 to 10 minutes. Use film manufacturer's specifications to determine the amount of time to leave film in fixer tank. Film should be agitated for the first minute of fixation.
- 12. Remove film from fixer tank. Drain well over fixer or wash water tank. Care should be taken not to drain fixer into developer tank.
- 13. Immerse film in wash water tank for 5 to 30 minutes.
- 14. If more than one film is being processed at a time be sure that films are as widely spaced as possible in the tank to ensure that the water can clear the fixer from the film. Water should be over top of film holder. Films should not touch each other.
- 15. Rate of water exchange in wash tank should be approximately eight times per hour. This will ensure fresh water to wash the chemicals from the film completely.
- 16. It is recommended to immerse film in a tank containing a wetting agent before drying. The wetting agent will minimize the water spots on the film.
- 17. Drain as much liquid from the film back into the wash water tank as possible before hanging film to air dry or placing in dryer.
- 18. If dryer is used, do not over dry film. Over drying film may cause cracking.
- 19. When dry, remove film from holder. Label film, if not previously done, with patient information.
- 20. Add fresh chemicals to tank to replenish the chemistry.
- 21. Cover tanks until next use.

Laser Film Printer Quality Control

<u> Test Frequency – Weekly</u>	
Standard	
SMPTE Test Pattern	Inverted gray scale
0% patch 2.45∀ 0.15 OD*	0% patch 2.50+ 0.15 OD
10% patch 2.10∀ 0.15 OD	10% patch 2.25∀ 0.15 OD
40% patch 1.15∀ 0.15 OD	40% patch 1.35∀ 0.15 OD
90% patch 0.30∀ 0.08 OD	90% patch 0.30∀ 0.08 OD
The 5% patch should just be vi	1
I V	visible inside of the 100% patch.

***OD = Optical Density**

In most clinical settings, the physician makes the diagnosis by reading the images from a transparency recorded with a multiformat camera. The transparency should reproduce the quality and gray scale of the original image displayed on the system monitor. The following procedure uses the Society of Motion Picture and Television Engineers (SMPTE) digital test pattern. This pattern is supplied with most laser printers or it can be obtained from accessory vendors.

As determined by procedure 3A, the laser film printer quality should be consistent over time and match the gray scales presented on monitor.

Procedure 3A Establishment of Laser Film Printer Quality Control Operating Levels

Frequency: Initial setup and when significant change is made in imaging procedures such as different type of film, chemicals, or processing conditions.

If possible, the medical physicist should assist with the initial establishment of the laser film printer quality control operating levels. The medical physicist should determine the most appropriate gray scale test pattern to use for the facility's laser film printer system configuration or acquire a stepwedge phantom image if no gray scale test pattern is available.

Equipment Required:

Densitometer Form 4 Laser Film Printer Quality Control Chart (page 76) Gray Scale test Pattern - SMPTE (Society of Motion Picture and Television Engineers)

A. Video Monitor Setup

Must be performed on EACH video monitor (operator's console, physician's console, etc.) so that the all appear similar.

1. Clean front surface of video monitor, including the front and back surfaces of any antireflective screens present, with a soft cloth and an appropriate cleaner.

- 2. Reduce room lighting to that usually used for viewing studies.
- 3. Display SMPTE test pattern on monitor.
- 4. Adjust the window width to just show the range of numbers of the test pattern.
- 5. Depending on the software, adjust the window level to either the lower or middle value so that the entire pattern is seen.
- 6. Turn both the brightness and contrast controls completely counterclockwise.
- 7. Turn the brightness control clockwise until the video raster pattern is just visible on the monitor.
- 8. Turn the contrast control clockwise until the image is bright and clear. Both the 95% and 100% patches must be clearly separated. Do not increase contrast beyond the point where the alphanumerics become blurred or streaked on the display.
- 9. The displayed image must show:
 - a. The 5% patch should be just visible inside the 10% patch.
 - b. The area of the 0% patch should be almost black with raster lines just barely visible.
 - c. The 95% patch should be visible inside the 100% patch.
 - d. The alphanumerics should be clear and sharp.

10. Record the window and level settings so that they can be used for the Weekly Laser Film Printer Quality Control.

B. Laser Printer Setup

- 1. Print the test pattern on film using the most commonly used image format (4 on 1, 6 on 1).
- 2. With the film on a view box and the same image on the monitor, visually compare the film gray scale densities on the film to those on the monitor.
- 3. Make necessary adjustments to the laser film printer settings to match film appearance to monitor appearance using manufacturer's recommended procedures. Also compare a variety of digital patient images printed on film with the same images as displayed on the monitor. This will ensure that the patient images appear the same on the monitor and on film.
- 4. Ensure that the 5% patch is just visible inside of the 0% patch and the 95% patch is just visible inside of the 100% patch.
- 5. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.
- 6. Measure the optical density with the densitometer at four different gray level steps on the film. Measure the optical densities (OD) of the 0%, 10%, 40%, and 90% patches.
- 7. Record the OD values on the Laser Film Printer Quality Control Chart (Form 4).

Procedure 3B Weekly Laser Film Printer Quality Control

Frequency: Weekly

Equipment Required:

Densitometer Form 4 Laser Film Printer Quality Control Chart (page 76) SMPTE (Society of Motion Picture and Television Engineers) test pattern (this test pattern is usually supplied with the laser printer or it can be purchased from a vendor)

- 1. Display the gray scale test pattern on the monitor and verify that the window and level settings have been set to values established in **Procedure 3A Establishment of Laser Film Printer Quality Control Operating Levels**.
- 2. Print the image on film using the image format established in **Procedure 3A**.
- 3. Ensure that the 5% patch is just visible inside of the 0% patch and the 95% patch is just visible inside of the 100% patch.
- 4. Record on Laser Film Printer Quality Control Chart (Form 4).
- 5. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.
- 6. Measure the optical density with the densitometer at the same four gray level steps on the film that were established in **Procedure 3A**.
- 7. Record the OD values on the Laser Film Printer Quality Control Chart (Form 4) and determine if any of the data points exceed the control limits.
- 8. Circle the out-of-control data points, determine and correct the cause of the problem and repeat the test, note the cause of the problem in the remarks section of the Laser Film Printer Quality Control Chart (Form 4) and plot the in-control data point.
- 9. Determine if there are any trends, i.e., three or more data points moving in one direction (either upward or downward). If trends are present but the data points have not, as yet, exceeded the control limits clinical images can be processed. However, it will be necessary to determine the cause of the trend and to monitor the laser film printer closely to ensure that the control limits are not exceeded.

An example of a completed **laser Film Printer Quality Control** chart can be found in the FORMS section as Form 4A (page 77)

CORRECTIVE ACTION: Immediate action must be taken to correct any problems. When a density step is found to be out of control limits, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until processor is operating within limits set by the regulations. All corrective actions must be completed before patient films are taken, documented and records retained for a minimum of 2 years.

Records: The Laser Film Printer Quality Control Chart (Form 4) must be kept for 1 year.

Darkroom Cleanliness

<u>Test Frequency - Weekly</u> <u>Standard - Free from dust and dirt</u>

The darkroom is a major source of problems in any radiographic facility. Dust or dirt in the darkroom can result in artifacts in the radiographic image. A clean darkroom reduces artifacts and the amount of effort required for cleaning the cassettes and screens. The following are some tips on darkroom maintenance:

- 1. No smoking, eating, or drinking in the darkroom.
- 2. The counter top used for loading and unloading the cassettes should be clear of unnecessary items.
- 3. Clutter makes cleaning more difficult and provides a place for dust and dirt to accumulate.
- 4. There should be no shelves above the counter tops in the darkroom.
- 5. The ceiling of the darkroom should be constructed of a solid material such as drywall. Ceiling tiles, often set in metal channels, allow dust and dirt to shift through the ceiling and fall on the surfaces used for handling cassettes. In addition, light can often enter the darkroom through such tiles, resulting in fog on the radiographic film.
- 6. The heating and air conditioning vents should not enter the room over the counter used for handling cassettes.
- 7. Cassettes stored on the floor will accumulate dust that may be carried into the darkroom. Cassettes should not be placed on the floor between exposure and being taken into the darkroom for processing.
- 8. The passbox, if present, should be cleaned every day to prevent dust and dirt from being introduced into the darkroom.
- 9. Keep hands clean to minimize fingerprints and handling artifacts.

Procedure 4 Darkroom Cleanliness

Equipment Required: Wet mop and pail Lint-free towels Liquid hand soap

- 1. Wipe or vacuum overhead air vents and safelights before cleaning the feed tray and counter tops.
- 2. Remove all items from the counter tops and work surfaces. If possible find a storage place for these items outside of the darkroom.
- 3. Use a clean, damp towel to wipe off the processor feed tray and the counter tops and other surfaces in the darkroom. Wipe all other items stored in darkroom.
- 4. Mop the darkroom floor.

(Note! This test is not required for the Polaroid Instant film System.)

Records: None required.

Processor Maintenance and Chemical Solutions

<u>Test Frequency - Initially and every 2 months (more frequently if needed)</u> Standard – Manufacturer's specifications

Maintenance and cleaning procedures generally involve the removal of all racks from the processor, inspection of the components for proper alignment and function, changing the water filter, changing the chemicals, etc. All manufacturers of processors provide product specific publications with the details of these steps. These procedures are usually performed by the processor service company.

If the facility wishes to perform their own processor maintenance and changing of chemicals, the manufacturer's procedures should be obtained and followed explicitly. Care must be taken when removing racks to avoid damaging them. Drip trays and splashguards should be used when removing or replacing racks to avoid contamination of the developer and fixer. When using system cleaners or changing chemical solutions, protective clothing (rubber gloves, goggles with side shields etc.) should be worn.

Used processor chemicals or cleaners must be disposed of according to environmental regulations. Call the NJ DEP Division of Environmental Regulation, Water Quality, Bureau of Pre-Treatment and Residuals at 609-633-3823 or the local sewage authority for restrictions and requirements.

Records: Record on Form 5 Quality Control Log-Bimonthly Tests (page 78) and maintain for 1 year.

Owners of the Polaroid Instant Film System must follow the manufacturer's recommendations for maintenance.

Facility's Equipment Visual Checklist

<u>Test Frequency - Initially and quarterly thereafter</u> Standard - All tests passed

The purpose of this checklist is to ensure that the X-Ray system is working properly and that the mechanical rigidity and stability of the equipment is maintained. The following is a list of items that should be checked. This list is generic. Items should be added or subtracted as they apply to the specific piece of equipment being evaluated. Each item should function as the manufacturer intended.

Procedure 6A Equipment Visual Check List

Equipment Required: Form 9 Facility's Equipment Visual Checklist(s) (page 82) **NOTE:** a separate checklist should be completed for **each piece** of equipment – OR – Form 9 should be modified to include more than one unit per checklist.

- 1. Review all of the items on the visual checklist and indicate their status. Each time a task is completed, the individual carrying out the task should write the date and their initials in the appropriate area on the checklist.
- 2. Record on Facility's Equipment Visual Checklist (Form 9) and maintain record for 1 year.

CORRECTIVE ACTION: Have repairs done on any item as necessary. All corrective actions must be completed within 30 days, documented and records retained for at least 2 years.

CONTROL PANEL: All controls and indicators on the control panel must function. Lights must light. Meters must activate appropriately.		
Meters	kVp, mA or other meters must function	
Displays	All numbers/letters on LCD panels must be functional and legible	
Indicator lights	KVp, mA, time: selected technique factor light must light	
Fixed Technique Factors	If equipment has fixed technique factors, such as kVp or mA, each must be legibly labeled. Labels must indicate correct kVp or mA	
AEC Display	All numbers/letters must be legible	
Exposure Switch	Depression of exposure switch must cause x-ray production. Release of switch must cause x-ray production to cease immediately. Check also that x-ray on light lights and/or buzzer sounds to indicate x-ray production	

COLLIMATOR/INDICATORS/LOCKS		
Illuminator	Light bulb must work. An illumination of at least 15 foot candles is required. If light level decreases, service must be called.	
Locks and detents	Must prevent x-ray production when tube is not at correct SID When locked must hold tubes in position placed	
SID indicators	Markings must be legible. If tape measure, it must be present	
Field Sizing Controls	Moving sizing controls must increase/decrease size of light field	

TABLE	
Table movement	Movement must be smooth. Table must remain in position it is placed in.
Bucky movement	Movement must be smooth. Bucky must remain in position it is placed in.

GENERAL	
Cables	Cables must not be kinked, frayed, twisted or the covering ripped or cracked
Interlocks	Interlocks, if present, on doors must prevent x-ray production when door is open
Mechanical	Arms, tables, buckys, etc. must be checked for integrity and stability. They must not be warped, cracked, unstable, have loose screws or bolts. Arms holding x-ray tubes must not drift from position when placed for x-ray.

VIEW BOXES	
Luminance	luminance must be even over entire viewing area
Surface cleanliness	free of dirt, streaks, discolorations

View Boxes

View boxes are a vital link in the process of reading radiographic films. The accuracy of the diagnosis is affected by the conditions under which the radiographs are viewed. The luminance of the view boxes and the room illumination determine if the conditions for reading x-rays are optimal.

Fluorescent tubes decrease in brightness over time. It is advisable to replace fluorescent tubes every 12 to 18 months. All tubes in the view box bank should be replaced at the same time to ensure uniformity in color and luminance. In addition, all of the replacement tubes should be of the same type and color.

Procedure 6B is not required by state regulation and is therefore optional. However,

cleaning view boxes and replacing fluorescent tubes on a routine basis will improve the reading of radiographs and decrease artifacts caused by damaged or soiled view boxes.

Procedure 6B View Box Cleaning (Optional)

Equipment Required: Glass cleaning supplies

- 1. Clean the outside surfaces of the view box using window cleaner and soft paper towels.
- 2. Assure that all marks have been removed.
- 3. Check that viewbox cover is not discolored, cracked, warped or otherwise damaged. If damaged it should be replaced immediately.
- 4. Visually inspect the view boxes for uniformity of luminance.
- 5. Replace fluorescent tubes annually with tubes from the same lot number. If a bulb or tube burns out, it is recommended that all bulbs in that view box bank be replaced at that time.
- 6. Visually check the room illumination levels and assure that sources of bright light are not present in the room or being reflected from the view box surface.
- 7. The inside of the view box should be cleaned at least annually.

CORRECTIVE ACTION: Bulb replacement as needed.

Film & Chemical Shelf Life

<u>Test Frequency - Initially and quarterly thereafter</u> Standard - No expired film/chemicals used. Use film/chemicals with earliest expiration date first.

Facility must ensure film and chemicals are used before their expiration dates. As recommended by National Council on Radiation Protection (NCRP) report number 99, photographic materials should be stored at temperatures less than 24EC (75EF), preferably in the range of 15E to 21EC (60E to 70EF). Open packages of photographic film should be stored in an area with humidity ranging between 40% and 60%. Film should not be stored in areas where they can be exposed to chemical fumes, direct sunlight or radiation. A system that uses the method of "FIRST IN FIRST OUT" should be employed to ensure proper rotation of film and chemistry. Film should not be allowed to remain in the film bin past the expiration date.

IMPORTANT! New shipments of film should be checked and should not be accepted from the vendor unless it can be used before the expiration date.

Procedure 7 Film & Chemical Storage

- 1. Maintain inventory so that the first product in is the first product used.
- 2. Maintain temperature, humidity and storage conditions recommended by the manufacturer of the radiographic film and the manufacturer of processor chemicals.
- 3. The room temperature should be measured using a thermometer. The room humidity can be measured using a hygrometer. The temperature and humidity should be checked periodically. If maintaining a stable temperature and/or humidity is a problem, the appropriate service person (heating, air conditioning, processor, etc.) should be called to resolve the problem(s).

CORRECTIVE ACTION: If storage conditions exceed manufacturer's recommendations, take the necessary steps to resolve the problem. To prevent oxidation, mixed chemistry should not remain in replenisher tanks for more than 2 weeks. For automatic processors, replenishment tanks should have floating lids to help prevent evaporation. For manual processing, tanks should be covered when not in use.

Using film or chemicals with expired dates is a violation of the state regulations.

Film and chemicals that have reached expiration dates must be disposed of according to environmental regulations. Call the NJ DEP Division of Environmental Regulation, Water Quality, Bureau of Pre-Treatment and Residuals at 609-633-3823 or the local sewage authority or solid waste authority for restrictions and requirements.

Records: None required.

05/01/03

Light field/X-ray Field Alignment

<u>Test Frequency - Initially, thereafter quarterly AND after each service</u> Standard - Total mis-alignment of x-ray field to light field must not exceed 2% of the source to image distance (SID)

Test must be repeated after each bulb change to ensure that the light field accurately defines the x-ray field.

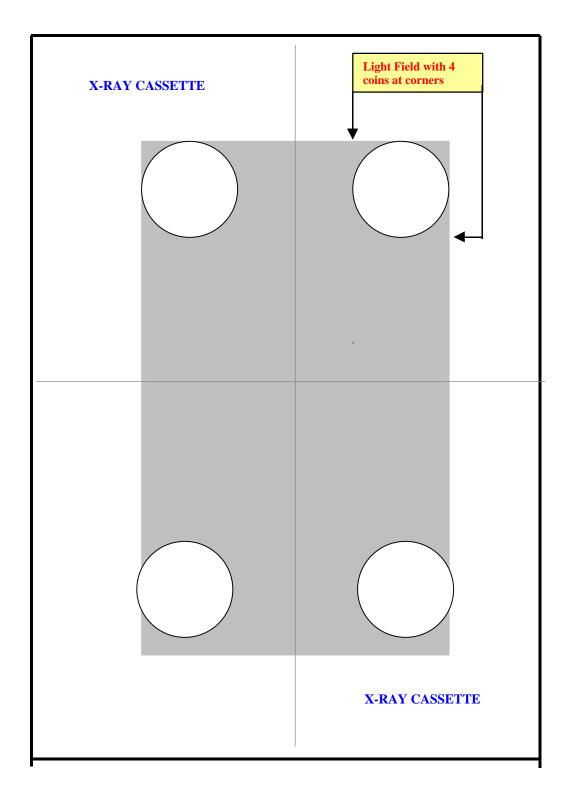
Procedure 8A X-ray Field/Light Field Alignment

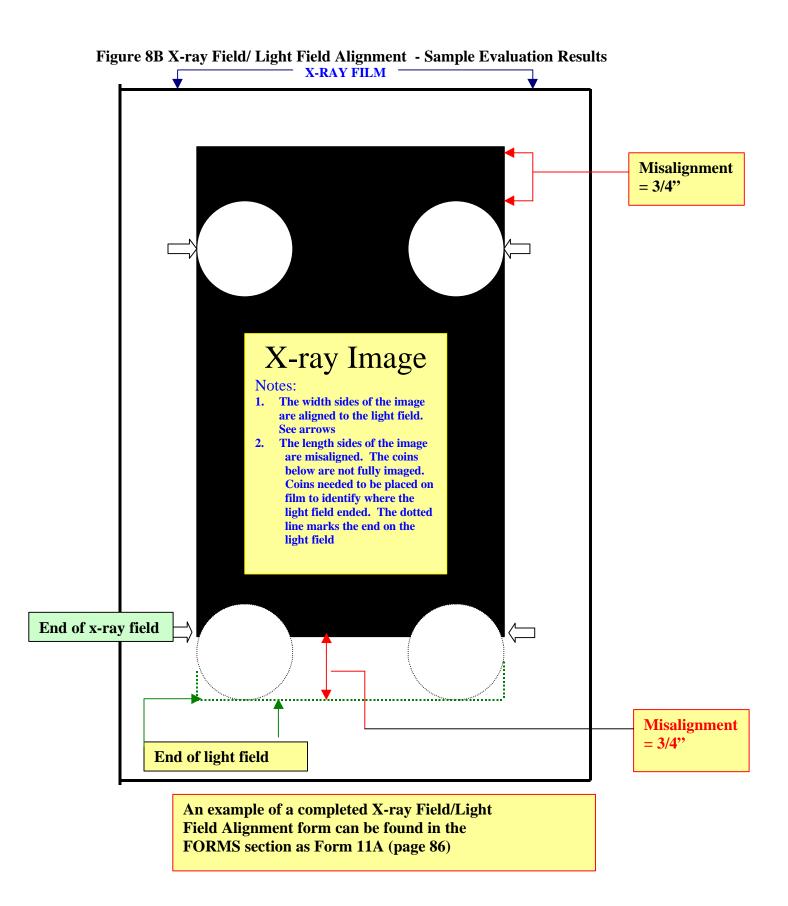
Equipment Required:

Opaque markers (coins) Cassette loaded with film Ruler Permanent marker Form 11 X-Ray Field/Light Field Alignment (page 85).

- 1. Place a cassette loaded with film on the tabletop. Set SID to 40" if possible.
- 2. Turn collimator light on, adjust the light field size to approximately 6" x 8". Light field edges should be straight, well defined and rectangular. If they are not, call service to adjust them.
- 3. Place opaque markers (Example: quarters) at each corner of the light field. Outside edge of marker should be on outside edge of light field with body of marker inside light field. See Figure 8A.
- 4. Make an exposure (use technique factors that will result in 2 mAs at 50 kVp).
- 5. Develop film.
- 6. If you cannot see entire marker within x-ray field, place the markers back on the film and draw around them.
- 7. Using Form 11 (page 85) and Figure 8B (page 37) as guides:
 - a. Determine 2% of the SID. Example: SID is 40" then (40)(0.02) = 0.8".
 - b. Measure the distance between the markers and one long side (L1) of x-ray field.
 - c. Measure the distance between the markers and the other long side (L2) of x-ray field.
 - d. Add the measurements from both long sides together. (L1 + L2 =)
 - e. Compare the answer in (d) to answer in (a). The answer to (d) must not be more than the answer in (a) for equipment to pass.
 - f. Measure the distance between the markers and one short side (S1) of x-ray field.
 - g. Measure the distance between the markers and the other short side (S2) of x-ray field.
 - h. Add the measurements from both short sides together. (S1 + S2 =)
 - i. Compare the answer in (h) to answer in (a). The answer to (h) must not be more than answer in (a) for equipment to pass.
- 8. Record on X-Ray Field/Light Field Alignment form (Form 11) and maintain record and film for 1 year.

CORRECTIVE ACTION: if light field and x-ray field fail, call a service company to repair. Retest after repair. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years. **SET-UP: Correct Placement of Coins**





Repeat Analysis

<u>Test Frequency – Semiannually (review rejected films immediately for corrective action)</u> Standard - None but goal should be less than 5% repeat rate.

While it is required that a facility calculate its repeat rate at least semiannually, the repeat analysis is an ongoing process. There are two steps to the repeat analysis. First, every time a film must be repeated, a review of why it was necessary to repeat the x-ray should be conducted. The reason for the repeat should be documented, then, twice a year, the repeat rate is calculated. By periodically reviewing the documented reasons why films are repeated, trends or frequent errors can be determined and steps can be taken to correct the errors. A carefully carried out repeat analysis will ensure quality radiographs by reducing the number of clinical films that are repeated. This analysis will help to identify ways to reduce both costs (wasted film and processor chemicals and wear on the equipment) and unnecessary radiation exposure and inconvenience to the patient. The facility should work towards a repeat rate of less than five percent.

Reasons for repeats are usually divided into three major categories:

- 1. EQUIPMENT including, but not limited to, inaccurate kVp, mA etc., light field/x-ray field misalignment, darkroom fog, and processor problems.
- 2. PATIENT including, but not limited to, motion, breathing, jewelry or other foreign objects, and other body parts overlapping area of interest.
- 3. X-RAY PERSONNEL ERROR including, but not limited to, improperly set techniques (kVp, etc.), improper collimation, improper positioning, and poor film handling.

In order to reduce repeats, it is necessary to know what studies (chest, abdomen, etc.) and projections (AP, lateral, etc.) are being repeated and why. <u>Immediate analysis is important.</u> The problems can then be addressed more efficiently. The analysis will demonstrate the strengths and weaknesses of the x-ray operation. The data from the repeat analysis is a valuable QA improvement tool.

ALL SUBSTANDARD FILMS SHOULD BE IMMEDIATELY ANALYZED FOR THE CAUSE OF THE REPEAT AND LOGGED ON THE REPEAT ANALYSIS FORM. THE DATA ARE USED TO CALCULATE THE **REPEAT RATE**.

There are a number of repeat analysis systems available commercially. While some are computerized, most usually consist of labels that are placed on the films at the time of rejection indicating the reason. A chart(s) is usually provided to tabulate results. These systems can be beneficial especially for facilities with a high volume. If the facility chooses to use a commercial system, follow the directions that come with the system to determine the repeat rate and not Procedure 9 "Repeat Analysis" on the following page.

The facility can also design a x-ray log that incorporates the repeat data into it.

Procedure 9 Repeat Analysis

Equipment Required:	Repeated films or a record of repeated films
	Form 10 Repeat Analysis Form (page 83)

Repeat analysis should be designed to accurately evaluate the type of radiographs being produced by the facility. Example: If the facility has students, the repeats from students should be evaluated independently from the other x-ray personnel.

Analyzing repeated films/exposures:

- 1. Review each exposure carefully as it is completed.
- 2. If any exposure needs to be repeated, the reason should be documented on the Repeat Analysis Form (Form 10) or what ever tracking system the facility is using.
- 3. The results of these reviews should be tabulated periodically. For large facilities, frequent (perhaps weekly) analysis is needed; smaller facilities will usually have fewer repeated films, so less frequent analysis is needed.
- 4. Identify the most frequent cause(s) for repeating exposures.
- 5. If any patterns are identified, take steps to resolve the cause of repeated films. Example: radiographs taken by technologist "Tony" were repeated because of poor positioning. Technologist Tony may need additional instruction on positioning.

Calculating the repeat rate:

- 1. At the beginning of the analysis period, record the number of sheets of unused film in the facility. If additional film is received during the analysis period, be sure to record the additional film on the form. For facilities with digital or computed radiography, be sure to include ALL exposures in analysis.
- 2. At the end of the analysis period, record the number of sheets of unused film remaining. Determine the number of films used (step one minus step two). Record on form.
- 3. Since each repeated film was evaluated and logged on the form at the time it was repeated, simply add up check marks for each category and record total on the data sheet
- 4. Add the numbers in each category to get the total number of repeated films. Determine the overall repeat rate by dividing the total number of repeated films by the total number of films used during the test period. (Note! For large volume facilities like hospitals, the repeat rate may be calculated by using a statistically significant sample. However, all repeated films must be evaluated immediately.)

An example of a completed repeat analysis form can be found in the FORMS section as Form 10A (page 84).

CORRECTIVE ACTION: The percentage of repeats should guide the facility to focus their efforts to those areas needing the most attention. For example, films that are too light or too dark may be due to processing problems or equipment problems that require repair or re-calibration, or technique charts may need updating. All corrective actions need to be documented.

Records: Maintain record of repeat analysis for 1 year.

Artifact Evaluation

<u>Test Frequency – Examine every film for artifacts, in-depth evaluation semiannually</u> Standard - No significant artifacts

All films should be examined for artifacts as they are produced. If an artifact is noted on any film, immediately investigate the cause and correct it. Prompt correction of the problem will ensure that the facility produces the best radiographs possible. It will also prevent small repairs from becoming larger and more costly repairs. Conduct an in-depth analysis semiannually.

Both an immediate artifact detection process and an in depth evaluation semi-annually is necessary due to the nature of medicine. The initial review is done as the radiographs are produced when making a diagnosis is most important. While gross artifacts, especially those in the area of interest (such as in the lung field of a chest x-ray) will be immediately noticed; small artifacts that do not detract from the diagnostic quality of the films may be missed. During the in depth evaluation, the registrant will look specifically for artifacts. These small defects should be noticed and their causes corrected. This in-depth evaluation will find problems such as deteriorating rollers before they cause major problems over large areas of the film.

Artifacts are marks on the film that do not contribute to or may decrease the diagnostic value of the film. They may in fact cause a misdiagnosis by either masking or imitating pathology. Artifacts must be kept to a minimum. As most artifacts are the result of improper film handling in the darkroom or processor problems, they can be easily minimized through a good quality assurance program. But first the artifacts must be recognized and their source determined.

Artifacts fall into four categories:

- 1. Darkroom problems, including film handling, darkroom cleanliness and darkroom fog.
- 2. Processor problems, including dirty rollers, light leaks, improper drying.
- 3. Patient caused artifacts, including clothing, jewelry, hair mousse.
- 4. Cassette and screen problems, including warping, cracking, discoloration and dirt or dust.

It is impossible to detail all the causes of artifacts in this manual or to give images to use for comparison. It is recommended that the facility purchase one of the books available on quality assurance and film processing that are available. Most have extensive sections with photos of various artifacts and their most likely causes. Review of these images will enable the facility to determine the source of the problem.

Alternatively you may wish to have the medical physicist, an imaging specialist or processor service company help you with the artifact evaluation. While artifacts may contribute to the repeat rate, the repeat analysis and the artifact evaluation are NOT the same procedure. The facility must perform both procedures.

Procedure 10 Artifact Evaluation

Equipment Required:

At least 5 films from <u>each</u> processor Magnifying glass Book on film artifact identification Form 6 Quality Control Log - Semi-Annual Tests (page 79)

- 1. Examine a large enough number of films to determine if there are artifact problems. At least 5 films from **each** processor should be examined.
- 2. Make note of all artifacts and their probable cause. Comparisons of artifacts with published examples are helpful to determine their cause.
- 3. Fix the problem that caused the artifact.
- 4. Review films taken after correction to ensure problem has been remedied.
- 5. Record on Quality Control Log Semi-Annual Tests (Form 6) and maintain record for 1 year.

CORRECTIVE ACTIONS: must be completed within 30 days, documented and records retained for a minimum of 2 years.

Some Common Artifacts And Their Causes					
ARTIFACT	POSSIBLE CAUSE				
Scratches	Dirt on counter top or feed tray Dirty or damaged processor rollers/guide shoes/turnarounds Stuck film which is scratching other films				
Fingerprints, smudges	Wet or dirty hands when handling film				
Crinkle marks (Finger nail)	Crescent shaped mark resulting from bending the film while loading or unloading film				
Partially exposed or fogged film	Light leak in darkroom or cassette Scatter radiation to cassettes left in x-ray room during exposure				
Trees (static)	Relative humidity is low and clothing generates static electricity which discharges onto film during handling				
Black spots	Film got wet or contaminated prior to processing Emulsion from pervious films transfers from dirty processor roller to film				
White spots	Dirty screens Emulsion pulled from film by dirty processor rollers Defect in film emulsion				
Brown film	Inadequate washing Inadequate fixing				
Water spots	Depleted chemicals in processor Poor squeegee action at wash rack exit Clogged dryer air tubes				

Analysis of Fixer Retention

<u>Test Frequency - Initially and semiannually thereafter</u> Standard - # 5-micrograms/sq. centimeter (or # 0.05 grams/sq. meter)

This test determines the quantity of residual fixer (hypo) remaining in processed film. It is an indicator of storage quality of the radiographs. Excessive fixer will degrade the quality of the image on stored radiographs.

The hypo estimator provides estimates of the amount of residual hypo in the film. The estimated amount of residual hypo should be 5 micrograms per square centimeter or less. The comparison should be made immediately after the excess test solution has been removed from the film. Waiting longer than 2 minutes to analyze the test will result in inaccurate results.

Excessive hypo retention indicates that the film is not being adequately washed. Possible causes are insufficient wash time or the wash water is not being exchanged fast enough.

Procedure 11 Analysis of Fixer Retention

Equipment Required:

Hypo test kit Eyedropper if not provided with hypo test kit Paper towels White paper Form 6 Quality Control Log – Semi-annual Tests (page 79)

- 1. Process one sheet of <u>unexposed film</u>.
- 2. Place one drop of the residual hypo test solution on the film.
- 3. For single sided emulsion film, place drop of the residual hypo test solution on the side with emulsion.
- 4. For dual sided emulsion film, you need only do one side of film.
- 5. Allow the solution to stand for two minutes.
- 6. Blot off excess solution with paper towel.
- 7. Compare the stain with the hypo estimator by placing the processed film on a sheet of white paper. The comparison should be made with the estimator over the film sample to help compensate for differences in the color of the base of the film and with the hypo estimator in its sleeve.
- 8. Record on Quality Control Log Semi-annual Tests (Form 6) and maintain record of 1 year.

CORRECTIVE ACTION: If the stain indicates that there is more than 5 micrograms per square centimeter residual hypo in the film, the test should be repeated. Check to see if the water for the processor is turned on. If the same result is obtained, contact the processor service company and have them service the processor. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years. (**Note! This test is not required for the Polaroid Instant film System.**)

Darkroom Fog

<u>Test Frequency - Initially, thereafter semiannually AND after each change to the</u> <u>darkroom</u>

Standard - # 0.05 Optical Density Difference

To ensure that the darkroom safelights and other light sources inside and outside of the darkroom do not contribute to the fogging of the radiographic film. This test should be repeated after each bulb change or any change in the darkroom that could affect darkroom fog conditions.

Procedure 12 Darkroom Fog

Equipment Required: Opaque card Densitometer Timer Radiographic film and cassette Form 6 Quality Control Log - Semi-Annual Tests (page 79)

- 1. Ensure that all safelight filters are those specified by the film manufacturer. The filters must not be faded or cracked. Also ensure that the bulbs are the appropriate wattage and the safelight is placed at the appropriate distance from the film handling area.
- 2. Turn off all the lights the darkroom and wait 5 minutes to allow your eyes to adjust to the darkness.
- 3. Look for obvious light leaks around doors, pass boxes, the processor and in the ceiling.
- 4. Correct all light leaks permanently before proceeding.
- 5. In total darkness (all safelights off), load the film into a cassette. If several different kinds of film are used, the fog test should be performed using the most sensitive film.
- 6. Place the cassette in the cassette holder of the x-ray equipment.
- 7. Collimate the x-ray field size to that of the cassette.
- 8. Make an exposure using the technique factors of 40-50 kVp and 1 or 2 mAs (400 speed film).
- 9. Be sure all lights in darkroom are OFF. Remove film from cassette. Place the exposed film on the counter top. Cover half the film with an opaque card so that the film is divided in half. Do not cover entire film.
- 10. Turn on all **safelights** for 2 minutes.
- 11. Process the film.
- 12. Using the densitometer, measure the density of the unfogged portion of the image (the part of the film that was covered) and the density of the fogged portion of the image (the part of the film that was not covered). Measure close (< 1") to the edge separating the fogged and unfogged portion of the cassette.

(Note! The optical density of the covered side of the film should be in the range of 1.4 to 2.0 on the densitometer. If it is greater or less, decrease or increase the mAs accordingly.)

Determine the amount of darkroom fog by subtracting the density measurement of the unfogged area from the density measurement of the fogged area. Darkroom fog should be no greater than 0.05.

13. If darkroom fog is greater than 0.05, repeat the test with the safelight off. If the results remain the same, a light leak is the probable cause of the problem. If the fog level disappears, the fog was due to the safelight.

14. Record on Quality Control Log - Semi-Annual Tests (Form 6) and maintain record and film for 1 year.

CORRECTIVE ACTION: Take appropriate action to correct the problem. Seal light leaks, replace safelight filter or bulb, etc. Retest to determine if fog is now at an acceptable level. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

(Note! This test is not required for the Polaroid Instant film System.)

Screen-Film Contact/Cassette Integrity/Screen Cleanliness

<u>Test Frequency - Initially and annually therefore or as needed</u> Standard - No areas of poor contact > 2 cm in diameter

Cassettes used for diagnostic examinations should be free of dust and dirt particles that may degrade image quality.

Each cassette-screen combination should have its own unique identification. This allows the identification of any cassette in which artifacts are noticed much easier. Each screen should be marked with a unique identifier near the edge of the screen using an opaque, permanent marker. The same identification number should also be placed on the outside of the cassette. Cassettes that contain artifacts should be cleaned and/or removed from service and/or replaced.

The film used must be matched to the screen's light output as specified by the manufacturer. In other words if the intensifying screen produces green light, the film should be sensitive to green light not blue light.

If the facility uses films of different speeds, the speed of the film must match the speed of the intensifying screen.

The manufacturers of the screens and film provides information on compatibility.

The manufacturer or film supplier should be consulted if the facility does not know the compatibility of the screens and film. It is not possible to derive this information independently.

Procedure 13A Film-Screen Contact

The procedure ensures that optimum contact is maintained between the screen(s) and film in each cassette.

Equipment Required: 1/8 inch mesh Brass or Copper Screen. The mesh can be placed between two thin sheets of acrylic or cardboard to protect it. All cassettes Form 7 Quality Control Log - Annual Tests Part 1 (page 80).

- 1. Load cassette to be tested and let rest for approximately 15 minutes to allow trapped air to escape.
- 2. Place cassette on the table and collimate the x-ray beam to the size of the cassette.
- 3. Place the wire mesh screen on top of the cassette and make an exposure. The optical density on the film should be between 1.0 and 2.0. Suggested technique is 1 or 2 mAs at 50 kVp.
- 4. Process the film.
- 5. View the film on a view box in a room with low ambient light. Stand 6 8 feet from the view box to evaluate the film.
- 6. Areas of poor contact will appear as dark areas or unfocused areas on the film.
- 7. Record on Quality Control Log Annual Tests Part 1 (Form 7) and maintain record for 1 year.

CORRECTIVE ACTION: Areas greater than 2 cm in diameter of poor contact indicate the need for corrective action. Clean the cassettes and retest. Areas of poor contact around the periphery of the cassette may indicate faulty latches or worn seals on the cassette. If cleaning does not eliminate the areas of poor contact, the cassette should be replaced. Most cassettes have a life expectancy of 10 years with adequate care. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

Procedure 13B	Cassette Integrity		
Equipment Required:	All Cassettes Form 7 Quality Control Log - Annual Part 1 (page 80)		

Cassettes must be in good physical condition in order to prevent light leaks that will fog film.

- 1. Examine each cassette. Cassette should be in good physical condition with no cracks, dents or other damage.
- 2. Check hinges. Cassette should close fully and easily. There should be no gaps around edges of cassette.
- 3. Check latches. They should work easily to open cassette. They should close and lock easily.
- 4. Open cassette. Check condition of screens and grids. Screens and grids should not be cracked, broken or discolored.
- 8. Record on Quality Control Log Annual Tests Part 1(Form 7) and maintain record for 1 year.

NOTE: If screens are damaged but cassettes are in good condition, contact service company and inquire if screen can be replaced.

CORRECTIVE ACTION: replace or repair damaged cassettes immediately. If screens or grids appear damaged, they should be replaced. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

Procedure 13C Screen Cleanliness

Equipment Required: Screen cleaner (as recommended by the manufacturer of the screens) Lint-free gauze pad, equivalent lint-free cloth, or camel hairbrush. Canned air All cassettes Form 7 Quality Control Log - Annual Tests Part 1 (page 80)

- 1. Visually inspect the condition of the intensifying screen.
- 2. Dust the screen with the camel hairbrush and canned air.
- 3. If foreign material (e.g. dirt, developer solution) can not be readily removed with a camel hairbrush or canned air, use liquid screen cleaner.
- 4. After cleaning with manufacturer approved cleaners, screens should be allowed to air-dry, standing vertically, before returning the cassette to use.
- 9. Record on Quality Control Log Annual Tests Part 1 (Form 7) and maintain record for 1 year.

CORRECTIVE ACTION: If the screen shows signs of cracking, fading or discoloration, it should be replaced. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

Lead aprons, gloves, gonadal and thyroid shielding integrity check

<u>Test Frequency - Initially and annually thereafter</u> Standard - No breaks in protective garments

Examine the integrity of the personnel shielding devices to ensure optimal protection to the patient when positioned properly. This is a good opportunity to remind staff of the necessity of using personnel shielding on themselves and patients.

NOTE: Lead aprons should never be folded. Cracks in the lead lining can develop at the fold, reducing the useful life of the apron.

Do not assume that brand new aprons, gloves, etc. contain no defects. Visual examination is not sufficient to ensure integrity of shielding. New aprons, gloves, etc. should be examined under x-ray immediately upon arrival and returned to supplier if defects are found.

Procedure 14 Lead Shielding Integrity Check

Equipment required:

Personnel shielding devices Form 7 Quality Control Log - Annual Tests Part 1(page 80).

If an image intensified fluoroscopy unit is available.

- 1. Lay out the item to be checked on the table.
- 2. Examine the entire item using the fluoroscope.
- 3. Look for radiation leakage which indicates breaks in the lead lining.
- 4. Record on Quality Control Log Annual Tests Part 1 (Form 7) and maintain record for 1 year.

If an image intensified fluoroscopy unit is not available.

- 1. Closely inspect each item for breaks, cracks, creases and irregularities. Run your hands over the surface of the item pressing firmly. You may feel damage that you cannot readily see.
- 2. Take a radiograph of suspect areas.
- 3. Process the film and look for radiation leakage that indicates breaks in the lead lining.
- 4. Record on Quality Control Log Annual Tests Part 1(Form 7).

CORRECTIVE ACTION: Any item displaying breaks in the lead lining should be replaced. All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

Medical Physicist's Radiographic QC Survey

<u>Test Frequency - Initially and annually thereafter</u> Standard - as required in N.J.A.C. 7:28-22.8

The registrant must ensure that a qualified medical physicist has performed and documented all the tests in Table 3. Record on Form 8 Quality Control Log - Annual Tests Part 2 (page 81) and maintain record (QC Survey) for 2 years.

CORRECTIVE ACTION: All corrective actions must be completed within 30 days, documented and records retained for a minimum of 2 years.

	Medical Physicist's Radiographic QC Survey Requirements				
Item	Test	Standard			
1	Radiographic Unit Assembly Evaluation	As required at N.J.A.C. 7:28-15.3			
2	Collimation Assessment	As required at N.J.A.C. 7:28-15.3			
3	Collimator Illumination	As required at N.J.A.C. 7:28-15.3			
4	Half Value Layer	As required at N.J.A.C. 7:28-15.3			
5	MA Exposure Linearity	As required at N.J.A.C. 7:28-15.3			
6	KVp Accuracy/Reproducibility	As required at N.J.A.C. 7:28-15.3			
7	Timer Accuracy/Reproducibility	As required at N.J.A.C. 7:28-15.3			
8	Automatic Exposure Control, Reproducibility, Tracking, Density Control	As required at N.J.A.C. 7:28-15.3			
9	Entrance Skin Exposure (ESE) Measurement	Determine ESE for common exam and compare with National Evaluation of X-ray Trends (NEXT) data available beginning on page 70-71 of this document.			
10	Image Quality Evaluation (Recommendation)	Established standard for phantom test tool used			
11	Review Facility/Technologist QC Test Records	Review QC tests for proper procedure and corrective action			
12	Physicist Report and Recommendations	Communicate results and recommendations to registrant			

TABLE 3

Quality Assurance Program Review

<u>Test frequency - Initially and annually thereafter</u> Standard - As required in N.J.A.C. 7:28-22.4(a) 7

The Quality Assurance Program must be reviewed in its entirety to ensure that all information is current and accurate. The review must occur annually or after any equipment or personnel change. If personnel or operating procedures change frequently, reviews should be conducted more frequently to ensure that facility's Quality Assurance Program is maintained.

Physician should review the QA program when it is initially established, after each change in personnel, equipment or policy and annually. A good time for the review is right after the Medical Physicist performs the annual QC Survey. Any changes can be reviewed with the Medical Physicist.

Record on Form 8 Quality Control Log - Annual Tests Part 2 (page 81) and maintain record for 2 years.

NOTE: most of the following list is taken from the requirements in N.J.A.C. 7:28-22.4 and are contained in the facility's QA Program Manual. There are additional items listed that should be reviewed at least annually to ensure that the facility is in compliance with all applicable sections of N.J.A.C.7:28.

Quality Assurance Program Review Requirements Review and update as necessary the following information:

- 1. List of clearly identified individuals and assigned responsibilities for maintaining the quality assurance program and for performing the quality control tests.
- 2. Quality Control (QC) measures
 - a. QC Tests to be performed and the frequency of each test
 - b. List of equipment to be tested
 - c. Acceptability limits for each test performed
 - d. Description of each QC test procedure
 - e. Sample forms for each QC test performed
 - f. Processor and solutions maintenance
 - g. Annual Medical Physicist's QC Survey
- 3. Policies and Procedures:
 - a. Policy for holding patients and for presence of individuals in room during radiation exposure
 - b. Policy for pregnant patients and employees
 - c. Policy for gonadal shielding
 - d. A description of the orientation program for operators of radiographic equipment including the duration and content of that program
 - e. Procedures for proper use and maintenance of equipment
 - f. Policies and employee responsibilities concerning personnel radiation monitoring
 - g. Policy for releasing films
 - h. Policy for labeling films (i.e., patient's statistics, facility information)

- i. A commitment to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed x-ray equipment within 60 days of installation and an initial Medical Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a)
- j. Policy for using technique charts
- k. Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a) 8
- 4. Corrective actions
 - a. A plan for repairing or calibrating the x-ray equipment
 - b. A plan for repairing or servicing the processor
- 5. Records keeping:
 - a. Records for the most recent one year of the QC tests performed by the registrant
 - b. Records of the initial Medical Physicist's QC Survey plus the two most recent QC Surveys
 - c. Records of corrective actions for the most recent two years
 - d. Personnel monitoring records. Per New Jersey Administrative Code 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment plus 10 years.
- 6. Reference manuals (if any) and their location.
- 7. A provision describing how the registrant and the qualified medical physicist will review the QA program annually.
- 8. Have you purchased new x-ray equipment either as a replacement or an additional unit? If so, did you:
 - a. Register it with the Bureau of Radiological Health within 30 days of installation?
 - b. Have a qualified individual perform a Radiation Safety Survey of the Environs and submit a copy to the Bureau of Radiological Health within 60 days of installation?
 - c. Have an initial Medical Physicist QC Radiographic Survey performed within 30 days of installation?
- 9. Review of each **Registration of a Radiation Producing Machine** form to be sure the information is current. Questions to ask yourself:
 - a. Have you moved?
 - b. Are you the owner of record?
 - c. Has the facility contact person changed?
 - d. Is the x-ray machine on the Registration form the one you are currently using?
 - e. New Jersey Administrative Code 7:28-3 requires that the Bureau of Radiological Health be notified **in writing** within 30 days of a change of any of the information on the Registration form.
- 10. Review of the **Radiation Safety Survey of the Environs for each x-ray unit** to ensure it is current. Questions to ask yourself:
 - a. Has the location of the equipment been changed?
 - b. Has any change been made to the room in which the x-ray is located?
 - c. Has the number or type of x-rays taken increased significantly?
 - d. Has there been any change in what the rooms surrounding the x-ray room are used for?
 - e. Any such changes should be reviewed with your medical physicist to determine if a new Radiation Safety Survey of the Environs needs to be performed. New Jersey Administrative Code 7:28 requires that a qualified individual perform a Radiation Safety Survey of the Environs and a copy submitted to the Bureau of Radiological Health within 60 days of any such change.
- 11. Are your registration fees paid for the current and previous year?
- 12. If any person other than a licensed practitioner takes x-rays, is each such person licensed as required by N.J.S.A.26: 2D-24 and N.J.A.C. 7:28-19? You may call 609-984-5890 to check the license status of any individual who is not a New Jersey licensed physician, podiatrist, or

chiropractor. **IMPORTANT:** Only New Jersey licensed physician, podiatrist, or chiropractor, or a New Jersey licensed diagnostic radiologic technologist is permitted to operate any type of medical diagnostic x-ray equipment and position patients for radiological procedures. **"Operate"** means the use or manipulation of x-ray equipment in any way that leads to or causes the emission of radiation or affects the amount or quality of radiation that is received by a patient. Examples of "operate" include, activating or terminating the x-ray exposure, setting or adjusting technical factors, setting the mode of imaging, setting the camera rate, and setting or adjusting the collimator. Tasks associated with turning on the x-ray equipment at the beginning of the day without a patient on the table, resetting the five minute timer, adjusting the imaging monitor, and post exposure data processing are not considered operating x-ray equipment. **"Position patients"** means the alignment of the x-ray tube, image receptor (image intensifier) and the area of the patient intended for exposure to radiation.

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TESTS

The chart on page 58 lists the equipment a facility needs to perform the QC tests.

as sensitometer and densitometer, may need to be purchased. A list of vendors for these items is listed in the VENDORS section on page 59.

PROCEDURE	EQUIPMENT REQUIRED	FORM NUMBER	
Equipment Warm-up Procedure	None	None	
Processor Quality Control (Sensitometry/Densitometry)	Sensitometer Densitometer Digital thermometer	1, 2, 3	
Laser Film Printer Quality Control	SMPTE test pattern Densitometer	4	
Darkroom Cleanliness	Wet mop and pail Lint-free towels Liquid hand soap	None	
Processor Maintenance	None	5	
Equipment Visual Checklist	None	9	
Film and Chemical Shelf Life	None	None	
Light Field/X-ray Field Alignment	Opaque markers Cassette loaded with film Measuring Tape Permanent marker	11	
Repeat Analysis	None	10	
Artifact Evaluation	Magnifying glass Book on artifact identification (optional)	6	
Analysis of Fixer Retention	Hypo test kit Paper towels White paper	6	
Darkroom Fog	Opaque card Densitometer Timer Radiographic film and cassette	6	
Screen-Film Contact	1/8" Brass or cooper screen All cassettes	7	
Cassette Integrity	All cassettes	7	
Screen Cleanliness	Screen cleaner Lint-free gauze pad or camel hairbrush Canned air All cassettes	7	
Lead Aprons, Gloves, Gonadal and Thyroid Shield Integrity Check	All personnel shielding devices	7	
Medical Physicist's QC Survey	None	8	
Quality Assurance Program Review	None	8	

VENDORS LIST

The following listing of vendors is supplied for informational purposes only. The State of New Jersey does not certify or license vendors. Inclusion in this list does not imply endorsement or recommendation by the New Jersey Department of Environmental Protection or any other state agency. A firm's name being absent from the list does not indicate that the Department has judged the firm unsuitable to provide services.

Sensitometer and Densitometer Calibration Vendors					
Vendor Name and Phone No.	Recommended Frequency	Cost	Turnaround Time	Loaner Available	
Nuclear Associates 516-741-6360	annual	\$ 185	2 –3 weeks	Yes with a charge of \$ 82 for each 30 days for either a sensitometer or a densitometer	
Innovision 800-850-4606	annual	\$ 135	1–2 weeks	Limited number of loaners available. First come - first served	
X Rite 616-534-7663	annual	\$ 120 and up depending on model	1 week	Limited number of loaners available. First come - first served	
JRT 610-327-9610	annual	\$ 150 and up depending on model	2 - 3 weeks	No	

Company	Address	City	State	Zip	Phone	Fax
Andrews & Walsh X-ray Inc.	55 Cannonball Rd	Pompton Lakes	NJ	07442	973-616-7100	
Cares Medical, Inc.	75 Manchester Ave	Key Port	NJ	07735	732-739-8900	732-739-0316
Diagnostic Imaging, Inc.	8015 Rt. 130 S.	Delran	NJ	08075	856-461-4261	
Elscint, Incorporated	86 Orchard Ave	Hackensack	NJ	07601	201-750-3240	
GE Medical Systems, Inc	PO Box 414	Milwaukee	WI	53201	800-558-5102	accessories
GE Medical Systems, Inc	PO box 1561	King of Prussia	PA	19406	610-992-6400	
Hi-Tech X-ray Inc.	2 Oak St	New Brunswick	NJ	08901	732-448-9729	732-448-9733
Marconi Medical Systems	595 Miner Rd	Highland Heights	ОН	44143	800-635-9729	
Marconi Medical Systems	2520 Metropolitan Dr.	Trevose	PA	19047	215-322-9300	
Marconi Medical Systems	4 Esterbrook Ln	Cherry Hill	NJ	08003	856-424-3620	
Med-X Imaging, Inc	1102 Industrial Parkway	Brick	NJ	08724	732-458-4144	732-458-4334
Metropolitan X-ray Supply	28 Eaton Rd	Eatontown	NJ	07724	732-544-9272	732-544-1845
New Jersey X-ray Corporation	40 Schuyler Ave	Kearny	NJ	07032	201-998-0909	
New Jersey X-ray Corporation	330 Belleville Tnpk	N Arlington	NJ	07031	201-998-0900	201-998-3903
Nuclear Associates	120 Andrews Rd.	Hicksville	NY	11801	888-466-8257	
PTW NEW YORK CORP	201 Park Ave	Hicksville	NY	11801	516-827-3181	516-827-3184
Smith-Chapman Inc.	PO Box 378	Kearny	NJ	07032	201-998-8877	201-998-0988
Standard X-ray Sales Co.	60 Coit St.	Irvington	NJ	07111	973-374-2400	973-374-8435
United X-ray Inc.	1 Todd Circle	No Brunswick	NJ	08902	732-381-0407	
X-ray Solutions, Inc	230 Mountain Ave	Middlesex	NJ	08846	732-356-1234	732-560-1988

Options For When The Facility's Sensitometer and/or Densitometer Is Unavailable

The NJ regulation specifies that processor QC MUST be performed every day that patient x-rays are taken.

The facility must ensure that if the sensitometer and/or densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the processor is operating within control limits before patient x-rays are taken.

The options given below are a TEMPORARY solution for times when the sensitometer and/or densitometer are unavailable. They are not to be used for longer than three weeks.

A facility should consult with their medical physicist or image consultant to determine which of the listed options is best for their facility. It is also possible for the medical physicist or image consultant to design another option for the facility to use while its sensitometer and/or densitometer is unavailable. Any such option must ensure that the processor is operating within control limits before patient x-rays are taken.

NOTE: It may be necessary to perform Procedure 2A (Establish Operating Levels and Control Limits) after the sensitometer and/or densitometer is calibrated or repaired if the density steps originally established are no longer the best choices.

Below is a list of options the facility may consider for meeting this requirement.

- 1. Obtain a loaner sensitometer and/or densitometer from a processor service company, the calibration company or arrange to use a colleague's. The facility must perform the following procedure to ensure that the Processor Quality Control Chart does not indicate an out of control processor due to the use of a different sensitometer and/or densitometer.
 - a. Dr. A has to return his densitometer for service. Dr. A asks Dr. B (whose office is in the building next door) if he can use Dr. B's densitometer. Dr. B agrees.
 - b. Dr. A exposes and processes a sensitometric strip as usual and takes it to Dr. B's office BEFORE performing any patient x-rays.
 - c. Dr. A reads his established steps for LD, MD, HD and Base + Fog using Dr. B's densitometer.
 - d. Dr. A compares the readings obtained in (c) to the readings he got previously with his own densitometer.
 - e. If the previous reading for the LD step was 0.53 and the LD step read with Dr. B's densitometer is 0.5, Dr. A will have to add 0.03 to all readings from Dr. B's densitometer in order to have comparable readings for his Processor QC chart. If the readings indicate that Dr. A's processor is out of control, Dr. A must correct the problem and perform steps (a) through (e) again to ensure his processor is operating within limits before taking patient x-rays.
- 2. Process patient x-rays with another facility's (such as a local hospital or colleague) processor. The facility must ensure that the processor used has had the Daily Processor QC performed and is in control before developing their films. Facility must ensure that the processing system in

use at the other facility is compatible (Chemicals, developing time, etc.) with their film. Facility must also ensure that the patient films are processed promptly with a little time as possible lapsing between the taking of the patient film and development. Holding films will result in poor quality images due to latent image development, possible film fogging, "forgotten" or mislabeled films, or double exposures.

- 3. It may be possible to use pre exposed sensitometer strips to cover the period that a sensitometer is unavailable. This procedure consists of producing the required number of sensitometric strips at one time before sending the sensitometer out for calibration or repair. The exposed but not <u>developed strips</u> must be stored in a light proof box. A strip would be developed each day and the steps visually compared. Please note that the DEP has not validated this procedure. It is important to consult with a medical physicist or image consultant in order to determine if this method will produce acceptable results for a particular facility.
- 4. Purchase two sensitometers and densitometers.
- 5. Send patients to another facility to have their x-rays.
- 6. Take no patient x-rays when facility has no operable/in calibration sensitometer and/or densitometer. The facility must not take patient films and hold them for processing until the sensitometer/densitometer is available. Holding films will result in poor quality images due to latent image development, possible film fogging, "forgotten" or mislabeled films, or double exposures.

NEXT DATA

The Nationwide Evaluation of X-Ray Trends (NEXT) is a national program conducted annually to measure the x-ray exposure that a standard patient receives for selected x-ray examinations. This program is conducted jointly by the Conference of Radiation Control Program Directors (CRCPD), an association of state and local radiation control agencies, and the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH).

Facilities are randomly selected and personnel from the participating states perform the surveys. Each projection is surveyed utilizing a clinically validated exposure equivalent phantom representing a standard reference patient. This standard NEXT patient stands 172 cm (5 ft, 8 in) in height, and weighs 74.5 kg (164 lbs.).

The Medical Physicist must compare a facility's entrance skin exposure (ESE) for chest, abdomen and LS spine examinations obtained during the Annual Medical Physicist's Radiographic QC Survey with the appropriate NEXT data or New Jersey ESE data.

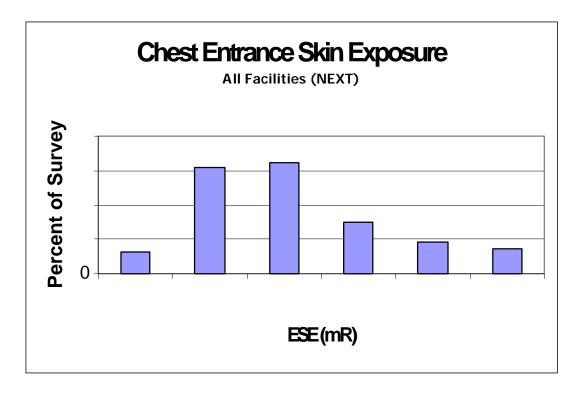
If the facility's ESE is at the upper end, lower end or outside the NEXT data range, the technique factors, film speed, film/screen match, etc. should be examined in order to determine if changes can be made (i.e. lower kVp) that will bring the ESE into the central portion of the graph. It is hoped that facilities at the upper end will consider technique or system improvements that will result in less radiation exposure to the patient without compromising image quality.

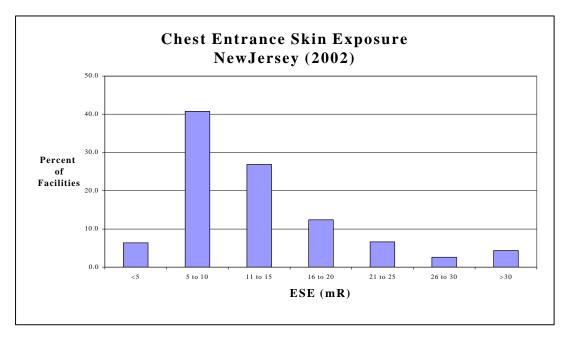
The information contained in the NEXT surveys is for guidance. The implementation and use of the information and recommendations are at the discretion of the user.

Following shown below is ESE data for foot exposures DEP inspectors recently measured. The standard foot used for these measurements is 8 cm. In the absence of NEXT data for foot exposures, the medical physicist may use the foot data below.

1994 PA Chest NEXT Data

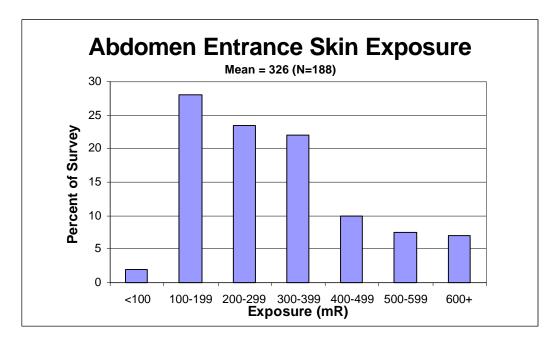
This standard NEXT patient stands 172 cm (5 ft, 8 in) in height, and weighs 74.5 kg (164 lbs.). The phantom used for chest is equivalent to a patient thickness, measured P/A, of 23 cm (9 in). Over 300 facilities were surveyed.

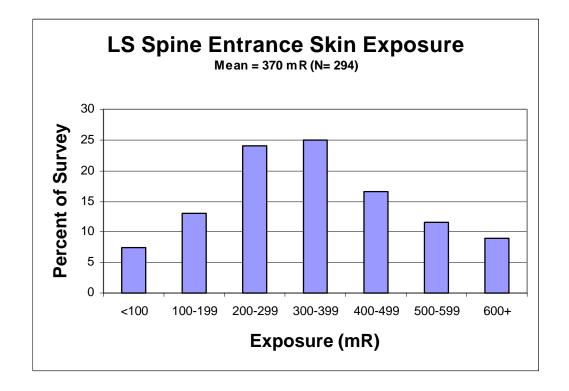


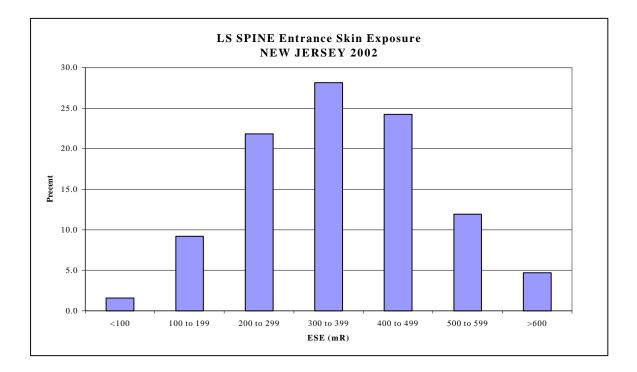


1995 Abdomen and LS Spine NEXT Data

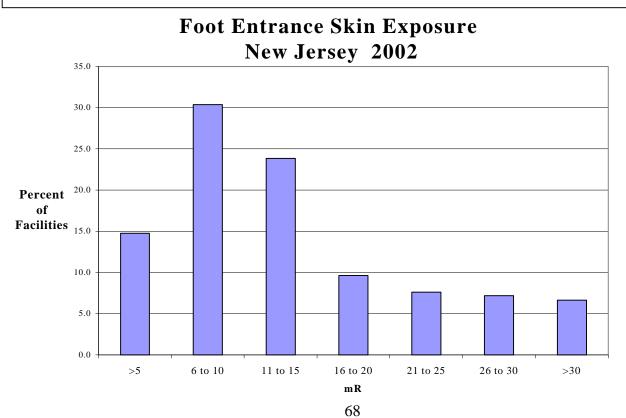
This standard NEXT patient stands 172 cm (5 ft, 8 in) in height, and weighs 74.5 kg (164 lbs.). The phantom used for abdomen and LS spine surveys is equivalent to a patient thickness, measured P/A, of 23 cm (9 in). Over 300 facilities were surveyed.







Since there is no NEXT data on foot ESE, the Department is providing below ESE data on foot exposures collected in New Jersey in 2002. The chart below may be used for ESE comparison when foot radiography is the primary procedure used at the facility. The Department considers a foot ESE between 5 mR and 30 mR to be within the average range. Foot ESE between 31 mR and 40 mR is considered high, with improvement recommended. Foot ESE greater than 40 mR is considered extremely high, needing remedial action.



05/01/03

FORMS

Processor: ______ Film: ______ Year: ______ Month Day Performed by Developer Temperature DD = Step – Step +0.15+0.10+0.05Density Difference -0.05 -0.10 -0.15 Mid Density Step = +0.15+0.10+0.05Mid Density -0.05 -0.10 -0.15 Base + Fog Step = +0.03Base + Fog -0.03 Date Remarks/Action Taken

Processor Quality Control Chart

Dute	

Form 1

Form 1A Processor:											2	3456			Ye	ear:		2001_				
Month		4	4	4	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	6	6	6
Day		20	21	22	25	26	28	2	3	4	10	11	15	16	17	19	23	30	31	1	5	6
Performed by		сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	сс	*
Developer Temp	perature	95	95	95	99	95	95	96	95	95	96	95	95	95	95	95	95	96	95	95	95	
DD = Step 13	3 – Stej	p 9					1	1														
2.08	+0.15																					
	+0.10																					
	+0.05																					
Density	1.93	\backslash												$\left\{ \cdot \right\}$		h						
Differen	ice		\searrow	\bigcap	arphi			$\left \right\rangle$	$\left[\right]$		1		\wedge		\bigvee		\searrow	$ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$		\searrow	[
	-0.05									V												
	-0.10																					
1.78	-0.15																					
Mid Density	Step = 1	12				•						•			•					•	•	
1.96	+0.15																					
	+0.10				•						\odot											
	+0.05									~												
Mid 1.81	L			\wedge		$\left[\right]$				$\left[\right]$		\sim							\searrow		-	
Density			\bigvee		\bigvee		\bigvee				Ń	/		\sim		\searrow	1					
	-0.05																					
	-0.10																	•				
1.66	-0.15																					
0.23	+0.03																					
Base + Fog	0.20	\mathbf{n}		\wedge									\wedge					\sim		_		
			\square						\sim										\sim			
0.17	-0.03																					
Date								R	ema	rks//	Actio	n Ta	ken									
					Remarks/Action Taken																	

Date	Remarks/Action Taken
4/25	Developer temperature too high. Lowered to 95E
5/10	Lowered replenishment rate
5/30	Raised replenishment rate
6/6	*Cross over performed. New processor QC chart started

Form 2 Establishing Film Processor Operating Levels Worksheet

Record all 21-density readings for each strip under the appropriate step and B+F (Base plus Fog)

Step #	2	4	6	8	10	12	14	16	18	20	B+F
Strip1											
Strip 2											
Strip 3											
Strip 4											
Strip 5											
Average											

Determine the Mid-density (MD). This is the step with an average density <u>closest to but not less than 1.20.</u> Determine the High-density (HD). This is the step with an average density closest to 2.20. Determine the Low-density (LD). This is the step with an average density closest to but not less than 0.45.

Determine the Density-difference (DD). Subtract the LD from the HD.

	Mid-density (MD)	High-Density (HD)	Low-density (LD)
Step #			
Average density			

Density difference (DD) = HD - LD

Form 2A Example of a completed Establishing Film Processor Operating Levels Worksheet

Step #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	B+F
Strip1	.20	.20	.20	.21	.21	.25	.27	.35	.47	.70	1.14	1.81	2.43	2.92	3.38	3.79	3.89	3.94	4.08	2.08	4.09	.20
Strip 2	.21	.21	.21	.22	.22	.26	.28	.36	.48	.70	1.16	1.83	2.40	2.91	3.34	3.78	3.91	3.95	4.07	4.10	4.10	.21
Strip 3	.20	.20	.20	.21	.22	.25	.28	.34	.46	.68	1.13	1.79	2.38	2.90	3.36	3.76	3.85	3.93	4.07	4.10	4.10	.20
Strip 4	.20	.20	.20	.21	.22	.25	.27	.35	.47	.71	1.15	1.82	2.41	2.91	3.35	3.78	3.90	3.95	4.09	4.09	4.09	.20
Strip 5	.20	.20	.20	.21	.21	.24	.26	.34	.46	.70	1.14	1.80	2.39	2.90	3.35	3.79	3.89	3.95	4.08	4.09	4.10	.20

Record all 21-density readings for each strip under the appropriate step and B+F (Base plus Fog) Determine average for each step and B+F.

Average	.20	.20	.20	.21	.21	.25	.27	.35	.47	.70	1.14	1.81	2.40	2.91	3.36	3.78	3.89	3.94	4.08	4.09	4.10	.20	
---------	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	------	------	------	------	------	------	------	------	------	------	------	-----	--

Determine the Mid-density (MD). This is the step with an average density <u>closest to but not less than 1.20</u>. Determine the High-density (HD). This is the step with an average density closest to 2.20. Determine the Low-density (LD). This is the step with an average density closest to but not less than 0.45. Determine the Density-difference (DD). Subtract the LD from the HD.

	Mid-density (MD)	High-Density (HD)	Low-density (LD)
Step #	12	13	9
Average density	1.81	2.40	0.47

Density difference (DD) = HD - LD 1.93
--

Form 3 Cross-Over Data Sheet

		Old Emulsion Data							
	Old Emulsion #								
	Base + Fog	MD	LD	HD					
Strip 1									
Strip 2									
Strip 3									
Strip 4									
Strip 5									
Average									
	· · · · ·			·					
	Dens	ity Differe	ence = HD	- LD					
		DE) =						

Date Performed:

Determining Differences Between Old and	
New Emulsions	

	Base + Fog	MD	DD
New Emulsion Average			
Old Emulsion Average			

Difference (New-Old)			
-------------------------	--	--	--

Determining New Operating Level from Old Level and Differences

	Base + Fog	MD	DD
Difference (New-Old)			
Old Operating Level			

New Operating Level		
(Diff +Old)		

Form 3A Example of a completed Cross-Over Data Sheet

Date Performed 2/17/00

	Old Emu	lsion Data	L		New Emu	ulsion Dat	a	
	Old Emul	sion # 123	4		New Emu	lsion # 56	78	
	Base + Fog	MD	LD	HD	Base + Fog	MD	LD	ŀ
Strip 1	.20	1.80	.47	2.43	.18	1.78	.51	2.48
Strip 2	.20	1.82	.48	3.44	.19	1.77	.52	2.47
Strip 3	.20	1.81	.48	2.41	.19	1.79	.50	2.46
Strip 4	.20	1.82	.47	2.40	.18	1.77	.51	2.47
Strip 5	.20	1.82	.49	2.41	.19	1.78	.51	2.48
Average	.20	1.81	.48	2.42	.19	1.78	.51	2.47
			·				·	
	Den	sity Differ	ence = HD	- LD	Den	sity Differ	ence = HD	– LD
	DD =	1.94			DD = 1.	.96		

Determining Differences Between Old and New Emulsions

	Base + Fog	MD	DD
New Emulsion Average	.19	1.78	1.96
Old Emulsion Average	.20	1.81	1.94

Difference (New-Old)	- 0.01	- 0.03	+ 0.02
-------------------------	--------	--------	--------

Determining New Operating Level from Old Level and Differences

	Base + Fog	MD	DD
Difference (New-Old)	- 0.01	- 0.03	+ 0.02
Old Operating Level	.20	1.81	1.93

New Operating Level (Diff +Old)	.19	1.77	1.95
---------------------------------------	-----	------	------

Form 2

Year:										Fi	lm:							
	<u> </u>										T 1	Γ	Γ	Γ	T 1	T 1	<u> </u>	
Day											<u> </u>	<u> </u>	<u> </u>		<u> </u>	<u> </u>	<u> </u>	
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	2.45																	
	2.3																	
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10%	2.25										L	Ĺ	L	L	L	L	[
									[]	[]	L	Ĺ	L	L	L	L	[
	2.10																	
	1.95																	
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7570 VISIOLO IN 100	570					<u> </u>	<u> </u>	I	<u>اــــــــــا</u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
Date							Rer	marks	/Acti	on Ta	ken							
2 410								11002	/	0								

Form 4 Example of a Completed Laser Film Printer Control Chart

Year:2	.001	Laser	Film F	rinter:	4				Fi	lm:	_ABC		_	
Month		4	4	4	4	4	5	5	5	5	6	6	6	6
Day		2	9	16	23	30	7	14	21	28	4	11	18	25
Initials		CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC	CC
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	0.38			<u> </u>				•						1
	0.50	I	I	Ι	Ι	I	1	I	I	I	1	1	I	<u> </u>
5% visible in	n 0%	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
95% visible		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Date						Rema	rks/Act	ion Tal	ken					
4/16	New film													
5/14		aser printer serviced, recalibrate												
6/4	recalibrat	e												

Form 5 Quality Control Log - Bimonthly Tests

Page _____ of _

Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes.

$\mathbf{P} = \mathbf{PASS}$		$\mathbf{Y} = \mathbf{Y}$	ES		0					
Processor Maintenance &	Performed by									
Chemicals (page 30)	If equipment failed, appropriate person(s) notified									
	Date									
	Performed by									
	If equipment failed, appropriate person(s) notified									
	Date									
	Performed by									
	If equipment failed, appropriate person(s) notified									

Form 6 Quality Control Log - Semi-Annual Tests

Page _____ of __

Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes. Performance and results of repeat tests should be listed on chart.

$\mathbf{P} = \mathbf{PASS}$	F = FAILED	$\mathbf{Y} = \mathbf{Y}\mathbf{E}\mathbf{S}$	N = 2	NO					
Repeat Rate	Date								
Calculation (Procedure 9)	Performed by								
(Page 38) Form 10, Page 82	Repeat Rate Calculated								
Artifact Evaluation	Date								
(Procedure 10)	Performed by								
(Page 40)	If equipment failed, appropriate person(s) notified								
	Date								
Analysis of fixer Retention	Performed by								
(Procedure 11) (Page 43)	If artifacts present, appropriate person(s) notified								
Darkroom Fog	Date								
(Procedure 12) (Page44)	Performed by							 	
	If equipment failed, appropriate person(s) notified								

Form 7 Quality Control Log - Annual Tests Part 1

Page _____ of _

Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes. Performance and results of repeat tests should be listed on chart.

P = PASS	F = FAILED	$\mathbf{Y} = \mathbf{Y}\mathbf{E}$	S	N = I	NO					
	Date									
Screen-Film Contact	Performed by									
(Procedure 13A) (Page 47)	If equipment failed, appropriate person(s) notified									
	Date									
Cassette Integrity	Performed by									
(Procedure 13B) (Page 48)	If equipment failed, appropriate person(s) notified									
	Date									
Screen Cleaning	Performed by									
(Procedure 13C) (Page48)	If equipment failed, appropriate person(s) notified									
Lead Apron,	Date									
Gloves, Gonadal and Thyroid Shield	Performed by									
Integrity Check (Procedure 14) (Page 49)	If equipment failed, appropriate person(s) notified									

Form 8 Quality Control Log - Annual Tests Part 2

Page _____ of _

Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes. Performance and results of repeat tests should be listed on chart.

$\mathbf{P} = \mathbf{PASS}$	F = FAILED	$\mathbf{Y} = \mathbf{Y}\mathbf{E}$	S	N = I	NO					
	Date									
Medical Physicist's QC	Performed by									
Survey (Page 50)	If problems found, appropriate person(s) notified									
	Date									
Quality Assurance	Performed by									
Program Review (Page51)	If problems found, appropriate person(s) notified									
	Date									
	Performed by									
	If equipment failed, appropriate person(s) notified									

Form 9 Facility's Equipment Visual Checklist

Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes and results recorded. P = PASS F = FAILED Y = YES N = NO

Person Performing Date							
pers	on(s) notified						
	Meters						
Control Panel	Indicator Lights						
	Fixed Technique						
	AEC Display						
	Illuminator						
Collimator/	Locks &						
Locks	SID Indicator						
	Sizing Controls						
Table	Bucky Movement						
General							
	Interlocks		 	 	 	 	
View boxes	Luminance						

Form 10 Repeat Analysis Form

 Date Analysis Began
 Date Analysis Ended

 Initial Film Count
 Ending Film Count
 Total Number of Films Used

 Analysis Performed By
 Total Number of Films Used
 Total Number of Films Used

Category	Number Of Films Repeated
Equipment	
Darkroom/Film Handling	
Processor	
X-Ray Unit Malfunction	
Other (specify)	
Other (specify)	
Patient	
Motion	
Other Body Parts on Film	
Jewelry/Foreign Objects	
Other (specify)	
Other (specify)	
X-ray Personnel Error	
Positioning	
Incorrect Markers/Patient ID	
Overexposed	
Underexposed	
Other (specify)	
Other (specify)	
Total Repeated Films	

Repeat Rate = <u>Total Repeated Films</u> = Total Exposed Films

Calculated Repeat Rate	%
------------------------	---

Comments:

Form 10A Example of a Completed Repeat Analysis Form

Date Analysis Began	1/1/0	00	Date Ai	nalysis Ended	6/30/00	
Initial Film Count	1000	Ending Film Count	306	Total Number o	f Films Used	694
Analysis Performed E	By Catherin	e H. Clawson				

Category	Number Of Films Repeated
Equipment	
Darkroom/Film Handling	7
Processor	9
X-Ray Unit Malfunction	0
Other (specify)	0
Other (specify)	0
Patient	
Motion	4
Other Body Parts on Film	2
Jewelry/Foreign Objects	3
Other (specify)	0
Other (specify)	0
X-ray Personnel Error	
Positioning	4
Incorrect Markers/Patient ID	1
Overexposed	5
Underexposed	2
Other (specify)	0
Other (specify)	0
Total Repeated Films	37

Repeat Rate = $\frac{\text{Total Repeated Films}}{\text{Total Exposed Films}} = \frac{37}{694} = 0.053 \text{ Or } 5.3\%$

Calculated Repeat Rate	5.3	%
------------------------	-----	---

Comments:

Form 11 X-ray Field/Light Field Alignment

Each time procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective actions taken. Procedures should be repeated after correction to ensure that equipment now passes and the results recorded.

To be performed quarterly (i.e. every 3 months) and after each corrective action including changing light bulb.

Date						
Pers	on performing					
Is th	is test performed after a corrective action?					
а	2% of SID = (SID)(.02) =					
	Measure distance between x-ray field and light field for each side					
b	Long side $1 = L1 =$					
c	Long side $2 = L2 =$					
d	L1 + L2 =					
e	Is answer in box d less or equal to the answer in box a? If yes, the long sides pass. If no, the long sides fail.					
f	Short side $1 = S1 =$					
g	Short side $2 = S2 =$					
h	S1 + S2 =					
i	Is answer in box h less or equal to the answer in box a? If yes, the short sides pass. If no, the short sides fail.					
	Check here if BOTH box e and box i are YES , equipment PASSES.					
	Check here if EITHER box e or box i is NO , equipment FAILS . Service must be called. After service repeat test. If equipment fails, notify appropriate person(s).					
Con	Comments:					

Form 11A Sample of a completed X-ray Field/Light Field Alignment Test

Each time procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective actions taken. Procedures should be repeated after correction to ensure that equipment now passes and the results recorded.

To be performed quarterly (i.e. every 3 months) and after each corrective action including changing light bulb.

Date	10/17/00							
Pers	on performing Catherine H. Clawson							
Is the	Is this test performed after a corrective action? NO							
а	2% of SID = (SID)(.02) = (40)(0.02) = 0.8 "							
Measure distance between x-ray field and light field for each side								
b	Long side $1 = L1 = 3/4" = 0.75"$							
c	Long side $2 = L2 = 3/4" = 0.75"$							
d	L1 + L2 = 1.5"							
e	Is answer in box d less or equal to the answer in box a? NO If yes, the long sides pass. If no, the long sides fail.							
f	Short side $1 = S1 = 1/4$ " = 0.25"							
g	Short side $2 = S2 = 1/4$ " = 0.25"							
h	S1 + S2 = 0.5"							
i	Is answer in box h less or equal to the answer in box a? YES If yes, the short sides pass. If no, the short sides fail.							
	Check here if BOTH box e and box i are YES , equipment PASSES.							
Т	Check here if EITHER box e or box i is NO , equipment FAILS . Service must be called. After service repeat test. If equipment fails, notify appropriate person(s).							
Con	Comments: Joe at X-rays R Us called on 10/17/00.							
Will	be out tomorrow							
	Dealer Information							

Dealer Information

A Walsh Imaging, Inc. 55 Cannonball Road Pompton Lakes, NJ 07442