

**New York State Department of Health
Bureau of Environmental Radiation Protection**

Guide for Radiation Safety/Quality Assurance Programs

Introduction

A. Purpose

This guide describes the type and extent of information and standards by which the New York State Department of Health will evaluate a facility's Radiation Safety/Quality Assurance Program.

Our Department has implemented this program to reduce radiation exposure and optimize diagnostic x-ray image quality. It is our goal to assist facilities to be more actively involved and responsible for Quality Assurance in their operations. It is important to review the program as a whole and not to become enmeshed in the everyday quality control tests. Facilities may substitute quality control tests if the tests are deemed equivalent by the Department prior to their implementation.

References can be found in the bibliography to assist you with test procedures and to answer questions not addressed in this brief guide regarding Quality Control and Quality Assurance.

B. ALARA Principle (As Low As Reasonable Achievable)

The regulations in Part 16 and this guide have been established on the ALARA Principle to assure that the benefits of the use of ionizing radiation exceed the risks to the individual and the public health and safety.

C. Control Limits and Standards

The control limits and standards used in this guide have been taken from the Federal Performance Standard for Diagnostic X-ray Equipment, Part 16, and other references listed in the bibliography. **Processor problems need to be addressed as they occur and before the limits are exceeded. Equipment problems should be corrected and documented expeditiously and shall be corrected with appropriate documentation within thirty (30) days of discovery.** The RS/QA program for Computed Tomography equipment is contained in a separate document.

D. Authority

The statutory authority for these rules and regulations is found in the New York State Public Health Law, Section 225. The Radiation Safety/Quality Assurance requirements are outlined in Section 16.5 and 16.23 of Part 16 of Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations. Please note that this program is in addition to and does not replace other sections of Part 16, which pertain to your operation.

Radiation Safety/Quality Assurance Programs

A. Radiation Safety/Quality Assurance Responsibility

Each facility shall establish a committee of individuals to be responsible for the Radiation Safety/Quality Assurance program. Hospitals will include those departments, which use x-rays for diagnostic purposes. This committee should be composed of a minimum of one radiologist, the Chief Technologist, the QC Technologist(s), and a Medical Physicist and a member of the in-house x-ray service or engineering group, if available. Individuals such as hospital administrators and representatives of contracted service companies may also be valuable. The committee in a non-hospital facility might be composed of a physician, radiologic technologist, office manager and service representative.

This oversight committee shall convene on a frequency adequate to meet their responsibilities, with a minimum of one meeting annually. More frequent meetings will probably be important in the initial stages of this program. The minutes of these meetings shall be kept for a minimum of three years.

It is the responsibility of this committee to provide direction to the program, assure that proper documentation and testing is maintained, review the program's effectiveness and determine any changes which should be made.

The committee shall assign Quality Control responsibilities in writing. Specific assignments shall be recorded in the manual. The responsible individuals shall be properly instructed. Evidence of continuing education shall be available for those individuals actively engaged in the Quality Control testing and evaluation process.

B. Records

1. Manual

Each facility will establish a manual that includes the following items:

- a. a list of the individuals responsible for testing supervising and repairing/or servicing the equipment;
- b. a list of the tests to be performed and the frequency of performance;
- c. the acceptability limits for each test;

- d. a brief description of the procedures to be used for each test (Appendix C-1 contains an example of a manual item on light field/x-ray field alignment);
- e. a list of the equipment to be tested;
- f. protocol for correction;
- g. reference materials and their location;
- h. a list of the equipment to be used for testing
- i. sample forms to be used for each test; and
- j. the committee organization and duties.

2. Equipment Records

Records shall be maintained for each x-ray room and mobile x-ray unit and include:

- a. the initial test results (acceptance testing and radiation safety survey as appropriate);
- b. the current year;
- c. one set of test results from each intervening year to show changes over time.

Records of repairs and other pertinent data shall also be available. It is not essential that the records be stored in the room with the x-ray equipment tested but must be easily accessible to anyone who needs to use them.

3. Radiation Output and Exposure Rate Measurements for Selected X-ray Examinations

The facility shall have available the radiation output measurements for common radiographic examinations they perform for patient and staff information for each x-ray unit. These measurements shall be repeated whenever changes are made to the system, which would impact the output. Appendix G is available for reference. Fluoroscopic exposure rates for the patient phantoms specified in Section 16.58(a)(9) of Part 16 for the most common examinations shall be posted so that they are conspicuous to the operator of each fluoroscopic unit.

4. Processor and Sensitometer Logs

Control charts of sensitometry shall be maintained and used to regulate processing.

Processor maintenance logs shall include preventive maintenance, corrective maintenance and cleaning (Appendix H). Each action shall be dated and initialed.

Processor charting of speed, contrast, and base + fog shall be graphed daily and posted as close as possible to the individual processor from which the data is derived. The graphs for each processor shall be kept for review for a period of time at least equal to the facility's inspection interval.

Facilities using dry image processing devices must evaluate those devices according to the manufacturer's recommended test procedures and test frequencies. The results of

the evaluation must be compared to the manufacturer's published specifications for that type of device. The results of those evaluations and any corrective actions taken must be retained for a period of time equal to at least the facility's inspection interval.

5. QC Records for Test Equipment

Records shall be maintained and available for review for QC test equipment, which requires calibration.

6. Radiation Safety Policies and Procedures

The written policy and procedures must be available for the holding of patients, use of gonad and scoliosis (if performed) shielding, pregnant patients and operators, personnel monitoring, x-ray screening and repeat, reject analysis. (Guidelines for information to be included can be found in Appendix F).

C. Equipment Monitoring

Each facility shall make or have made the following tests, at the frequency specified, and maintain records of the data. The type of tests and the frequency of the tests may be modified at the discretion of the Department if the facility can show documented proof that alternative tests or schedules will ensure good diagnostic image quality.

This guide describes a basic Radiation Safety/Quality Assurance Program and represents only a portion of the Quality Control tests your facility may choose to perform as part of an individualized program.

A chart of tests and frequencies can be found in Appendix A.

1. Test frequency – Each day of operation

Equipment functioning: Each day during the x-ray generator warm-up, and before x-raying the first patient, the operator should check for indicator dial malfunction and also the mechanical and electrical safety of the x-ray system. Malfunctions and unsafe conditions shall be corrected promptly. Suggestions for visual and manual checks are in Appendix H.

Film processing: For each day of operation, the processing system must operate as close to the film manufacturer's temperature and speed recommendations of the product as possible. It is very important that corrective action be made when limits are exceeded or a pattern develops indicating a degradation of the system.

Parameters to be included in processing checks:

- a. Speed Index or Medium Density:
Control limits +/-0.15 Optical Density O.D.
- b. Contrast Index or Density Difference:
Control limits +/-0.15 O.D.
- c. Base + Fog:
Maximum density shall not exceed the established control limit by more than 0.03 O.D.

Solution temperatures and replenishment rates should be checked when troubleshooting speed and contrast problems.

2. Test frequency – Quarterly

- a. Collimators
 - (1) Light field/X-ray Field Alignment (App. C-1)
The misalignment in either dimension of the edges of the light field versus the x-ray field shall not exceed 2% of the Source-Image-Distance (SID).
 - (2) Positive Beam Limitation (PBL) (App. C-2)
The x-ray beam size shall not differ from the image receptor size by more than 3% of the SID in any one dimension or by a total of more than 4% of the SID in both dimensions.
 - (3) X-ray Field/Image Receptor Alignment (App.C-3)
The misalignment of the center of the x-ray field as compared to the center of the image receptor shall not exceed 2% of the SID.
- b. Collimators – Fluorographic

This requirement applies to spot film and fluoroscopic beam size in worst case conditions.

- (1) Image Receptor/X-ray Field Alignment
 - (i) For image intensified equipment, the x-ray beam shall not exceed the visible area of the image receptor by more than 3% of the SID in one dimension or by a total of more than 4% of the SID in both directions.
 - (ii) For non-certified image intensified equipment, the x-ray beam shall not exceed the visible area of the one/one spot film.
 - (iii) For non-image intensified equipment, the x-ray field size shall not extend beyond the visible area of the image receptor.

3. Test Frequency - Semiannually

a. Radiographic Timer (includes Automatic Exposure Control)

(1) Reproducibility of the Output

Radiographic units or spot film devices are in compliance, if in field testing, it can be shown that for four exposures at a specific time:

$$\frac{X_{\max} - X_{\min}}{X_{\text{avg}}} \leq 10\%$$

where X is an exposure measurement in mR.

The most commonly used exposure time settings should be selected for testing. If the results of the four exposures are not compliant, make six additional exposures and calculate the coefficient of variation. The coefficient of variation of the exposure measurements shall be no greater than 0.05 and shall be determined by the equation:

$$\frac{S}{X} \leq 0.05,$$

where X is the average of the exposure measurements and S is the standard deviation of the exposure measurements.

(2) Accuracy

Certified equipment shall meet the manufacturers' specifications.

b. kVp Accuracy

Unless otherwise specified in the manufacturer's written specifications, all equipment shall meet:

- ± 2 kVp of the indicated for < 30 kVp,
- ± 3 kVp of the indicated for 31-100 kVp, and,
- ± 6 kVp of the indicated for > 100 kVp.

c. mA Linearity

For certified equipment, the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

That is $(X1-X2) \leq 0.10(X1+X2)$ where X1 and X2 are average mR/mAs values obtained at each of two consecutive tube current settings. A minimum of four (4) measurements shall be done at each of the mA stations. The generator should be capable of maintaining the above linearity across all the available mA stations.

d. Tomographic Equipment

Each tomographic unit shall be evaluated for:

(1) Slice or tomographic cut level.

The slice or cut level shall be within 5 mm of the indicated level.

(2) Slice or tomographic cut thickness.

The slice or cut thickness with an arc setting of 30° shall have a slice thickness of 2.0 or 2.5 mm.

(2) Uniformity of Exposure

For linear tomographic units, the exposure field using a pinhole trace, will demonstrate uniformity of exposure on both sides of the center of exposure.

For complex motion tomographic units (elliptical, circular, hypo-cycloidal, tri-spiral, etc.) the pinhole exposure trace shall not indicate any area of large gaps in exposure on the trace pattern nor shall it show erratic motion.

(3) Resolution

Each tomographic unit should be capable of resolving a #40 mesh pattern and shall be capable of resolving a #20 mesh pattern.

Facilities with two or more tomographic units shall maintain those units so that the slice or tomographic cut level is the same for each unit. It is recommended that for such facilities, a Littleton or comparable phantom be used to evaluate tomographic systems, in particular, those systems performing complex motion.

e. Fluoroscopic Image Evaluation

(1) Spatial Resolution

The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The minimum spatial resolution at the center of the beam for a 6 inch field of view (FOV) is 2 line pairs

per mm. The minimum spatial resolution for all other FOVs shall be determined by the following equation:

$$2 \text{ lp/mm} \times (6'' (15 \text{ cm}) \text{ FOV} / \text{size of the FOV used}) = \text{minimum number of lp/mm.}$$

(2) Low Contrast Performance

The low contrast performance of the fluoroscopic system shall resolve a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and 1½ inches of Type 1100 aluminum or an equivalent device.

f. Exposure Switch

At exposure times of 0.5 sec or more the switch must terminate the exposure if manual pressure is removed.

g. Interlocks

All interlocks shall forbid exposure when in the open position. This includes the fluoroscopic primary barrier, which shall be in position for use in order for fluoroscopic exposure to be possible.

h. Safelights/Darkroom Fog

An x-ray sensitized film should show less than 0.05 Optical Density (O.D.) in excess of the optical density due to the radiation exposure when exposed to a safelight exposure time of two minutes and shall not exceed 0.05 O.D. for one minute.

i. View Boxes

The brightness of the viewboxes used to check films after processing shall be within 15% of the brightness of the viewboxes used by the radiologists to read the films.

j. Lead Aprons, Gloves and Drapes

Protective garments and drapes shall not have tears, which impair their radiation protection function.

4. Test Frequency – Annually

a. Half Value Layer (HVL)

(i) For certified equipment, the minimum HVL shall not be less than:

X-ray Tube Voltage Designed Operating Range	kVp Measured	Al (mm)
Below 50	30	0.3
	40	0.4
	49	0.5
50-70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(ii) For non-certified equipment, the minimum aluminum equivalent of total filtration shall not be less than:

Operative kVp	Minimum Total Filtration (Inherent Plus Added)
Below 50	0.5 mm Al
50-70	1.5 mm Al
Above 70	2.5 mm Al

b. Timers – Fluoroscopic

(1) Certified equipment shall indicate with a signal audible to the operator the termination of a pre-set time interval, not to exceed five (5) minutes. When engaged, the signal must continue until the reset button is depressed. For uncertified equipment the passage of a preset time, not to exceed five (5) minutes, must be noted by a signal audible to the operator or an interruption of the fluoroscopic beam.

c. Fluoroscopic Exposure Rate Measurements

- (1) Exposure rate limits for certified fluoroscopic equipment manufactured before May 19, 1995:
 - Automatic Mode: 10 R/minute
 - Manual Mode: 5 R/minute
 - High Level Control (HLC) Mode: 5 R/minute (when not operating in HLC)
 - HLC Mode: 20 R/minute (when operating in HLC and not recording the image)
- (2) Certified fluoroscopic equipment manufactured after May 19, 1995 and capable of producing a radiation exposure rate in excess of 5 R/min must have automatic exposure rate control. Such equipment is limited to maximum exposure rate of 10 R/minute.
- (3) Certified fluoroscopic equipment manufactured after May 19, 1995 and having HLC must meet requirement (2). Such units are limited to 20 R/min when operating in HLC and not recording the image in a pulsed mode.
- (4) Uncertified fluoroscopic equipment is limited to a maximum exposure rate of 10 R/min.
- (5) The fluoroscopic exposure rate in automatic and/or manual mode must not exceed 5 R/min when measured with a patient equivalent phantom composed of 1½ inches of Type 1100 aluminum and 0.5 mm of copper or an equivalent device.

d. SID Indicators

The measured SID shall be within 2% of the indicated SID.

e. Film/Screen Contact

Film/Screen contact shall not indicate areas of poor contact in the center of the image receptor. Screens in use for over four years shall be evaluated annually for film/screen contact.

D. Technique Charts

Each x-ray unit shall have an appropriate technique chart located in a conspicuous position for reference by the operators. As a minimum this chart shall include patient size versus technique factors, SID, grid data, film/screen combination, gonad or breast shielding as appropriate and patient exposure. These charts must be updated when different film/screen

combinations are purchased and when new x-ray tubes or calibrations change the baseline data from which the charts were developed.

E. Log Book

Each facility shall maintain a log book or an equivalent record system containing the patient's name, date of exam, type of examination, number of views taken, amount of fluoroscopic on-time (if applicable) and when applicable the reason for holding the patient.

F. Repeat/Reject Analysis

Each facility shall conduct at least one reject analysis per year of their films. An ongoing repeat analysis should be conducted more frequently; e.g. monthly or quarterly. It is important that the facility follow the procedures established to assure that the studies are carried out in the same manner each time. Appendix D is available for reference.

G. Purchase Specifications and Acceptance Testing

Before purchasing new equipment, the facility is encouraged to determine the desired performance specifications for any new equipment including film, screens, and chemistry. Appendix E contains information which facilities may find useful in preparing performance specifications.

This information should be requested by the facility from each prospective vendor, so that the facility will be able to compare the advantages and disadvantages of competing systems.

H. Cassette Maintenance

Cassettes and screens shall be maintained to minimize the occurrence of artifacts. Screens should be inspected and cleaned regularly with the cleaning solution recommended by the screen manufacturer. The spectral characteristics of the light emitted by the intensifying screens must match the spectral characteristics of the film.

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LIST OF APPENDICES

	<u>Page</u>
Appendix A	
Quality Control Test Frequency	15
Appendix B	
Processor Problem Troubleshooting	16
Appendix C – Sample Test Procedures	
C-1 Light Field/X-ray Field Alignment	17
C-2 PBL	18
C-3 X-ray Field/Image Receptor Alignment	20
Appendix D	
Repeat-Reject Analysis	22
Appendix E	
Performance Specifications	23
Appendix F – Policy and Procedures	
F-1 Policy and Procedures for Patient Holding	25
F-2 Policy and Procedures for Pregnant Workers	26
F-3 Policy and Procedures of Use of Gonad Shielding	27
F-4 Policy and Procedures for Shielding Scoliosis Patients	30
F-5 Policy and Procedures for Pregnant Patients	31
F-6 Policy and Procedures for Personnel Monitoring	32
Appendix G	
Radiation Output Measurements	33
Appendix H	
Forms	34

APPENDIX A

Quality Control Test Frequency

Each Day of Operation

Equipment functioning
Indicators and mechanical and safety checks

Processing
Speed, contrast, and base + fog

Quarterly

Collimators
Light field/x-ray alignment
Positive Beam Limitation Sizing
X-ray field/image receptor alignment
Fluoroscopic image receptor/x-ray field alignment

Semi-annually

Radiographic timers including AEC
KVp
MA linearity
Fluoroscopic image resolution
Tomographic equipment
Exposure switches
Interlocks
Safelights/darkroom fog
View boxes
Aprons, gloves and drapes

Annually

HVL
Fluoroscopic timers
Fluoroscopic tabletop exposure rates
Film/screen contact
SID indicators

On Installation of New Equipment/Tube or Output Change

Radiation protection surveys
Acceptance testing
Average patient exposures for common x-ray examinations

APPENDIX B

Processor Problem Troubleshooting

Some day to day fluctuations in control values are to be expected. When these fluctuations exceed the control limits you should make sure that they are real and not just the result of an error. Repeat the monitoring procedures before taking corrective action. If the limits are still exceeded, immediate corrective action is required. Corrective action is also necessary when a trend indicates a degradation of the system. Below are some common problems and likely causes.

Increased Density Difference (Contrast) – High developer temperature; excessive replenishment rate; improperly mixed developer.

Decreased Density Difference (Contrast) – Low developer temperature; depleted, contaminated or improperly mixed developer; lack of starter in fresh developer; reduced replenishment; depleted fixer; safelights; film storage or handling.

Increased Medium Density (Speed) – High developer temperature; lack of starter in fresh developer; contaminated, depleted or improperly mixed developer; incorrect replenishment.

Decreased Medium Density (Speed) – Low developer temperature; reduced replenishment; weak developer; improperly mixed developer.

Increased Base + Fog – High developer temperature; safelight problems; film storage and handling problem; lack of starter in fresh developer; dirty rollers; contaminated developer; depleted fixer; improper replenishment.

Wet or damp films – Depleted fixer; developer either depleted, contaminated or diluted or the temperature too low; loss of circulation.

Dirty films – Water problems; dirty roller; developer problems; loss of circulation; misaligned guideshoes; film handling problems.

Scratches – Dirty rollers; misaligned guideshoes; depleted or diluted developer; fixer depleted; dryer problems.

APPENDIX C-1

Light Field/X-ray Field Alignment Test

Purpose

To assure that the x-ray field and light field are congruent.

Limits

2% of Source-Image-Distance (SID) misalignment along either the horizontal or vertical edges of the light field vs. the x-ray field. 2% of 40" = 0.8 inches

Test Frequency: Annually

SID: 40"

Technique Factors: 60 kVp, 5 mAs

Test Tools: Loaded 8"x10" or similar size cassette, 9 pennies

Procedures

1. Place loaded cassette on x-ray table.
2. Center light field to the center of the cassette at a 40" (100cm) SID.
3. Collimate beam to approximately a 5"x7" beam.
4. Mark the four sides of the light field. One method is to place two pennies together so that the pennies touch at the edge of the light field. Do this on each of the four sides. Facing the film, place a penny in the light field to identify the lower right corner of the film.
5. Expose and develop the film.
6. Examine each of the four sides of the exposed film. The inside pennies closest to the center of the field shall lie partially or completely in the radiation field. The outside pennies may partially lie in the exposed field but no outside penny may be fully covered by the radiation field.
7. Misalignment in either dimension (horizontal misalignment is the sum of the deviation of the right and left edges, vertical misalignment is the sum of the top and bottom edges) cannot exceed 0.8 inches. The deviations should be less than +/- 1/2 the diameter of the penny at any edge and must be less than +/- the diameter of the penny.

APPENDIX C-2

Positive Beam Limitation Sizing

Purpose

To assure that the automatic collimation system adjusts to the cassette size used.

Limits

The x-ray beam shall not differ from the image receptor size by more than 3% of the SID in any one dimension or a total of 4% of the SID in both dimensions.

Test Frequency: Annually

SID: 40"

Test Tools: One 8"x10" or similar size cassette, one larger cassette, film and a ruler.

Procedures

1. Place the empty, smaller cassette in the bucky tray.
2. Check that the collimator is in the automatic mode.
3. Set the SID to 40" and lock the vertical travel of the tube suspension.
4. Place the loaded, larger cassette on the tabletop. Center the tube longitudinally and transversely, check that the x-ray tube is perpendicular to the cassette. Activate the light localizer and center the x-ray tube to the bucky tray. Make sure that the cassette on the tabletop is centered as well.
5. Make an exposure and process the film from the larger cassette. If the exposed field size from the larger cassette does not exceed the film size in the bucky tray, the PBL system meets requirements. If the exposed field size from the larger cassette exceeds the film size for the cassette in the bucky tray, then **triangulation** utilizing the exposed film from the large cassette must be done to determine the actual field size at the bucky tray.

Triangulation

6. Measure the x-ray field along the table on the tabletop film and record.
7. Measure the x-ray field across the table on the tabletop film and record.

To determine the width of the field at the cassette in the bucky tray, complete the following formula:

$$\frac{W2}{D2} = \frac{W1}{D1}$$

W2 – width of x-ray field at film plane in bucky.
W1 – measured width of the x-ray field on the table top film.
D1 – measured source to tabletop distance.
D2 – the indicated SID of the unit (40”).

The result of this calculation will be the width of the x-ray field in the bucky tray.

8. To determine the length of the field at the cassette in the bucky tray, complete the following formula:

$$\frac{L2}{D2} = \frac{L1}{D1}$$

L1 – measured x-ray field length on tabletop film.
L2 – length of the x-ray field at the plane of the film in the bucky tray
D1 – measured source to tabletop distance.
D2 – the indicated SID of the unit (40”).

The result of this calculation will be the length of the x-ray field in the bucky tray.

The maximum misalignment can be calculated using the SID and the values identified under limits at the beginning of the previous page.

These numbers can be compared with the calculations made in determining the length and width of the field in the bucky tray.

APPENDIX C-3

X-ray Field/Image Receptor Alignment

Purpose

To assure that the x-ray field is centered to the cassette and the bucky tray.

Limits

The misalignment of the center of the x-ray field as compared to the center of the film shall not exceed 2% of the SID. 2% of 40" = 0.8 inches

Test Frequency: Annually

SID: 40"

Technique Factors: 70 kVp @ 10mAs

Test Tools: Loaded cassette, ruler

Procedure

1. Place a 8x10 cassette in the bucky tray, center the film in the tray, and lock into place.
2. Make sure that the x-ray tube is centered to the table using the transverse locking mechanism on the x-ray tube.
3. Center the bucky tray to the collimator centering light.
4. Set x-ray tube to 40" SID.
5. Manually collimate light field to leave ½ to 1 inch border on the film. This will leave an unexposed border on the film after processing.
6. Expose and process the film.
7. To find the center of the film, place a ruler at opposite corners of the film and draw a line. The point where the two lines cross is the center of the film. Because film has rounded edges, some estimating will have to be done when positioning the ruler in opposite corners.
8. To find the center of the exposed portion of the film, place the ruler at opposite corners of the exposed portion of the film and draw a line. The point where the two lines cross is the center of the exposed field.

9. Measure the distance between the center point of the film and the center point of the exposed field.

10. Record this information.

Compare the result to the acceptance limit previously identified. At a 40" SID, the maximum acceptable misalignment would be 0.8 inches.

APPENDIX D

Repeat-Reject Analysis

Purpose

To provide a method for the analysis of the rejected radiographs. The results of such an analysis will provide information concerning those aspects of radiologic imaging that need the most attention. If you plan to initiate a quality control program then you should carry out an analysis of your rejects before starting the QC program so you will have an idea of the impact of your efforts.

Equipment Needed

Rejected radiographs and a count of the total number of films consumed during the survey period.

Procedure

1. Start the test with an empty reject film container.
2. Establish a method to accurately determine the amount of raw film consumed starting on the day that you collect the reject film.
3. Decide on the length of the survey period. At the end of this period, collect all rejected radiographs and determine the actual number of radiographs exposed (i.e., the number of sheets of raw films consumed) during this period.
4. Analyze all of the rejected films and determine the reason that they were probably rejected. See Appendix H for an example.
5. Record these numbers on a tally sheet as you are reviewing the films. Don't be surprised if there are many radiographs for which you can't determine the cause of rejection. (Note: It will be difficult to determine if a light or dark radiograph was rejected because of poor technique or improper processing. Consequently, these must be classed simply as "light" or "dark".)
6. Determine the overall reject rate. For example, if there were 7 rejected films and a total of 122 films produced, then the overall rate is $7/122 \times 100\% = 5.7\%$.
7. Determine the percentage of rejects from each of the categories. For example, let's say that 3 films fell into the category labeled "too dark". The percentage of rejected films falling into this category is $3/7 \times 100\% = 43\%$.

Note: An "Analysis of Retakes: Understanding, Managing and Using an Analysis of Retakes for Quality Assurance", FDA 79-8097, is another excellent reference.

APPENDIX E

Performance Specifications Criteria

- A. Generator Voltage Supply
- B. Single or Three Phase Generators
- C. Generator Kilovoltage (kV)
 - 1. Kilowatt (kW) rating
 - 2. Maximum kV
 - 3. Minimum kV
 - 4. Accuracy of kV
 - 5. kV increments
 - 6. Line voltage factor (manual or automatic)
 - 7. Medium or high frequency
- D. Generator mA
 - 1. Maximum setting (small focal spot/large focal spot)
 - 2. Minimum setting (small focal spot/large focal spot)
 - 3. mA increments (small focal spot/large focal spot)
 - 4. mA accuracy
- E. Timing Controls
 - 1. Time selector increments
 - 2. Maximum setting
 - 3. Minimum setting
 - 4. Time selection display (fractional or decimal)
 - 5. Interrogation time
 - 6. Exposure termination time
- F. X-ray Tube
 - 1. Number of tubes
 - 2. Maximum kV rating
 - 3. kW ratings
 - 4. Rotational speed (60 or 180 hertz)
 - 5. Anode heat storage capacity
 - 6. Focal-spot size (small/large)
 - 7. Target diameter
 - 8. Target angle
 - 9. Heat dissipaters (fan or heat exchanger)
 - 10. Heat monitor (simulator or heat sensor)
- G. Automatic Exposure Control
 - 1. Response time
 - 2. Density control

3. Operates on all mA station
4. Tracking accuracy
5. Forced exposure termination
6. Number and location of chamber fields

H. Tube Hangers

1. Floor or ceiling mounted
2. Detents (mechanical or electrical)
3. Minimum source-image-distance
4. Measurement accuracy
5. Tube rotation

I. Collimators

1. Type (rectangular or combination fields)
2. Aluminum filtration equivalency
3. Added filtration
4. Slots for wedge filters
5. Tube angulation indicator
6. Alignment
7. Source-image-distance indicator

J. Auxiliary Equipment

1. X-ray exposure counter
2. Automatic high-speed rotation control
3. Tube overload indicator

APPENDIX F-1

Policy and Procedures for Patient Holding

The facility shall include the following information in its Policy and Procedures Manual item for those situations where patient holding may be necessary:

1. A list of the x-ray projections where holding devices cannot be utilized;
2. Who will hold;
3. The existing restraining devices available;
4. The use of protective garments; and
5. Where to find the log of those individuals who hold. This log will include date, number of views, and the name of the holder, their exposure and the reason holding was necessary.

APPENDIX F-2

Policy and Procedures for Pregnant Workers

The facility must use the requirements in Part 16 of 10NYCRR to establish their Policy and Procedure Manual item regarding pregnant employees.

The following information shall be included:

1. The method of instructing workers as to the requirements of Sections 16.2(a)(29) and 16.6(h) of Part 16 with regard to voluntarily declaring a pregnancy.
2. The method of ensuring that the embryo/fetus does not receive a monthly total effective dose equivalent of more than 50 mrem and total dose for the gestation period of more than 500 mrem.
3. The method of informing workers of their monthly exposure and total exposure for the gestation period.
4. The facility policy regarding work assignments for declared pregnant workers.

APPENDIX F-3

Policy and Procedures Regarding the Use of Gonad Shielding

The facility must use the requirements contained in Section 16.53(b)(6), 16.56(c)(3) and 16.57(c)(2) of Part 16 and may use the information provided in the attached Federal regulations for the administration of the “Radiation Control of Health and Safety Act of 1968” to establish their Policy and Procedures Manual item regarding the use of gonad shielding.

The following information shall be included:

1. The x-ray examinations which require gonad shielding;
2. The method(s) of shielding available; and
3. The age limit for use of gonad shielding.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1000--GENERAL

Subpart C--Radiation Protection Recommendations

Sec. 1000.50 Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used without interfering with the objectives of the examination to protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within or are in close proximity to the x-ray field. Such shielding should be provided when the following conditions exist:

(a) The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation. Except as provided in paragraph (b) or (c) of this section:

(1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;

(2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film;

(3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues and could adversely affect the quality of the radiograph; and

(4) Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by 0.25 millimeter of lead.

(b) The clinical objectives of the examination will not be compromised.

(1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within 5 centimeters of its edge. It is not always possible to position shields on male patients so that no bone is obscured. Therefore, if all bone structure of the pelvic area must be visualized for a particular patient, the use of

shielding should be carefully evaluated. The decision concerning the applicability of shielding for an individual patient is dependent upon consideration of the patient's unique anthropometric characteristics and the diagnostic information needs of the examination.

(2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels. However, it may be possible for practitioners to use specific area ovarian shielding during selected views in some examinations.

(c) The patient has a reasonable reproductive potential.

(1) Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.

(2) The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

Expected Number of Future Children Versus Age of Potential Parent \1-----

Age	Male parent	Female parent
Fetus.....	2.6	2.6
0 to 4.....	2.6	2.5
5 to 9.....	2.7	2.5
10 to 14.....	2.7	2.6
15 to 19.....	2.7	2.6
20 to 24.....	2.6	2.2
25 to 29.....	2.0	1.4
30 to 34.....	1.1	.6
35 to 39.....	.5	.2
40 to 44.....	.2	.04
45 to 49.....	.07	0
50 to 54.....	.03	0
55 to 64.....	.01	0
Over 65.....	0	0

\1\ Derived from data published by the National Center for Health Statistics, ``Final Natality Statistics 1970,`` HRA 74-1120, vol. 22, No. 12, Mar. 20, 1974.

[41 FR 30328, July 23, 1976; 41 FR 31812, July 30, 1976]

APPENDIX F-4

Policy and Procedure Regarding the Use of Shielding for Scoliosis Patients

The facility shall include the following information in its Policy and Procedures manual when a patient has films taken to evaluate scoliosis:

1. Methods to provide shielding of the gonads for all patients;
2. Methods to provide shielding of the breast for female patients;
3. Availability of compensating filters to decrease chest exposure; and
4. Use of dedicated cassettes with film/screen combinations decreasing patient exposure.

APPENDIX F-5

Policy and Procedures for Pregnant Patients

The facility shall include the following information in its Policy and Procedures manual item regarding pregnant and potentially pregnant patients:

1. Method of establishing which patients may be pregnant;
2. Policy for determining need for x-ray examination in pregnant patients;
3. X-ray techniques for minimizing fetal exposure;
4. Method of determining exposure to fetus; and
5. Procedures to be followed in advising the woman and her practitioner of the exposure received by the fetus.

APPENDIX F-6

Policy and Procedures of Personnel Monitoring

The facility using personnel monitoring shall include the following information in its Policy and Procedures manual:

1. The name of the person responsible for distribution, collection and records of badges;
2. The location of controls;
3. A prohibition against intentionally exposing the control or personnel badge; and
4. The location of records and policy regarding notification of personnel of exposures.

APPENDIX G

Radiation Output Measurements

<u>Projection</u>	200 Speed		400 Speed	
	<u>Aver.</u>	<u>Max.</u>	<u>Aver.</u>	<u>Max.</u>
A/P LS (40") – 23 cm	450	540	350	420
P/A Chest (72") – 23 cm	Grid	25 30	15	18
	Nongrid	15 18	5	6
Abd (KUB) (40") – 23 cm	490	588	300	360
Full Spine (72") – 23 cm	260	312	145	174
Cerv. Spine (40") – 13 cm	135	162	95	114
Lat. Skull (40") – 15 cm	145	174	70	84

Procedure for Chest or Spine

1. Center the x-ray tube to the tabletop or vertical cassette holder. Check that the proper SID has been selected.
2. For procedures done on the x-ray table, place the ionization chamber on the table. Center the chamber 23 cm from the top of the table.
3. For procedures using an upright cassette holder, the chamber is centered vertically to the cassette holder. Measure the distance from the front of the upright cassette holder to the center of the ionization chamber. The measurement must be 23 cm.
4. Check the light field from the collimator to make sure that the ionization chamber is completely covered. Collimate the beam to the field size used for the projection.
5. Select the technical factors that would be used to image a medium size patient who measures 23 cm thick.
6. Make an exposure and record the result. Record the values of three exposures and average these numbers.
7. The resulting number is the radiation output for the exam you have selected. Compare with the above chart. Radiation outputs may not exceed twice the average for the projection. Chest output measurements may not exceed 50 mR. This number should be recorded along with the technical factors and distances used and posted for reference.

APPENDIX H

FORMS

From: "Quality Control in Diagnostic Imaging" Gray, Winkler, Stears and Frank, Aspen Publishers, 1983

From: "Quality Control in Diagnostic Imaging" Gray, Winkler, Stears and Frank

Reject/Repeat
Analysis _____

Location _____
From _____ To _____

Cause	Number of Films	Percentage Of Rejects	Percentage Of Repeats
1. Positioning			
2. Patient Motion			
3. Light Films			
4. Dark Films			
5. Clear Film		 	
6. Black Film			
7. Tomo Scouts			
8. Static			
9. Fog – Darkroom			
10. Fog – Cassettes			
11. Mechanical			
12. Q.C.		 	
13. Miscellaneous (?)			
14. Good Films			
Total Waste (1-4) <input type="text"/> %	<input type="text"/>	 	
Total Rejects (All except 5 and 12)	<input type="text"/>	 	
Total Repeats (1-4, 6, 8-11, 14)	<input type="text"/>	 	
Total Film Used <input type="text"/>	<input type="text"/>		

From: "Quality Control in Diagnostic Imaging" Gray, Winkler, Stears and Frank

|Visual and Manual
|Quality Control Checks

Building: _____ Section: _____ Room #: _____ Tube: _____

OVERHEAD TUBE CRANE	TFD Indicator or marks																				
	Angulation indicator																				
	Locks (all)																				
	Perpendicularity																				
	Field light																				
	Bucky center light																				
	High tension cable/other cables																				
TABLE	Overhead crane movement																				
	Bucky lock																				
	Cassette lock																				
	Float and power top switches																				
	Measuring caliper																				
	Step stool																				
	Angulation indicator/stop																				
Foot board and shoulder braces																					
CONTROL BOOTH	Hand switch placement																				
	Window																				
	Panel switches/lights/meters																				
	Technique charts																				
	Overload protection																				
FLUOROSCOPIC SYSTEM	Locks (all)																				
	Power assist																				
	Motion smoothness																				
	Switches/lights/meters																				
	Compression device/spoon																				
	Fluoroscopic monitor																				
	Fluoroscopic grid																				
	Fluoroscopic timer																				
	Fluoroscopic drapes																				
	Park position interrupt																				
	Fluoro shutters visible – high																				
Fluoro shutters visible – low																					
OTHER	Gonad shield/aprons/gloves																				
	Bucky slot cover																				
	Pass = √ Fail = F Does not apply – NA																				
	DATE																				