New York State Department of Health  
Bureau of Environmental Radiation Protection  

Guide for Radiation Safety/Quality Assurance Programs in Small Facilities  

Part I – Radiographic Equipment  

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 practices. It is important to review the overall program and not become enmeshed in the 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.

This guide applies to medical and chiropractic facilities performing less than 2500 diagnostic radiographic examinations each year. Facilities performing more than 2500 studies each year are referred to the Department’s “Guide for Radiation Safety/Quality Assurance Programs”.

B. ALARA (As Low As Reasonably 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 sixty (60) days of discovery.
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 Sections 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 that pertain to your operations.

Radiation Safety/Quality Assurance Program

A. Radiation Safety/Quality Assurance Responsibility

The physician or chiropractor who registers the radiation equipment is responsible for radiation safety and quality assurance and the implementation of this program.

B. Records

1. Manual

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

a. a list of the tests to be performed and the frequency of performance;
b. the acceptability limits for each test;
c. a brief description of the procedures to be used for each test (see Appendix C);
d. a list of the equipment to be used for testing; and
e. sample forms to be used for each test.

2. Equipment Records

Records shall be maintained for each x-ray tube 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


The facility shall have available the radiation output measurements for common x-ray examinations they perform for patient and staff information for each x-ray unit. These measurements shall be repeated when changes are made to the system which effect the radiation output.
4. Processor and Sensitometer Logs (App. B and H)

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

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

Facilities with automatic processors must chart speed, contrast, and base + fog for each day processing is performed. Facilities with manual processing must chart these parameters every other day processing is performed or at a minimum of once a week and measure the temperature of the developer each day processing is performed. The graphs shall be kept for a period of time equal to at least 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 requiring calibration.


The written policy and procedures must be available for the holding of patients, use of gonad shielding, pregnant patients and operators and repeat, reject analysis. If applicable, policy and procedure items for personnel monitoring, use of breast shielding for scoliosis studies and x-ray screening, as defined in 16.22, shall also be prepared.

C. Equipment Monitoring

Each facility shall make or have made the following tests, at the frequency specified, and maintain records of the data. If at the time of inspection, significant equipment malfunctions are found the facility may be required to perform more frequent testing to ensure compliance with the program.

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, check for indicator dial malfunction and 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 as possible to the film manufacturer’s temperature and speed recommendations. It is very important that corrective action be made when the limits are exceeded or a pattern develops indicating a degradation of the system. Procedures for beginning an automatic processor program can be found in Appendix B. An occasional use processor is a processor that is used once a week or less.

   Parameters to be included in processing checks:

   **Automatic processors:**

   a. Speed Index or Medium Density:
      Control limits +/-0.15 Optical Density O.D.  
      Occasional use processors +/-0.20 O.D.

   b. Contrast Index or Density Difference:
      Control limits +/-0.15 O.D.  
      Occasional use processors +/-0.20 O.D.

   c. Base + Fog:
      Maximum density shall not exceed the established control limit by more than 0.03 O.D.

   **Manual Processors:**

   a. Every day of operation – Solution Temperatures

   b. Every other day of operation – occasional use must be at least once a week  
      Speed, contrast +/-0.15 O.D.  
      Base + fog same as automatic processors above.

2. **Test frequency – Annual**

   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. Safelights/Darkroom Fog (App. B-6)
A sensitized film should show less than 0.05 O.D. in excess of the optical density due to the radiation exposure when exposed to a safelight exposure time of 2 minutes and shall not exceed 0.05 O.D. for 1 minute.

c. Exposure Switch
At exposure times of 0.5 second or greater the switch must terminate the exposure if manual pressure is removed.

d. Interlocks
All interlocks shall forbid exposure while in the open position.

3. Test frequency – Every other year

a. Film/Screen Contact
Film/screen contact shall not indicate areas of poor contact in the center of the image receptor. Cassettes in use over 4 years shall be evaluated for film/screen contact.

b. Radiographic Timer (includes Automatic Exposure Control)

(1) Reproducibility of the Output
Radiographic units are in compliance, if in field testing, it can be shown that for four exposures at a specific time:

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

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.

c. Radiographic Timer Accuracy

Certified equipment shall meet the manufacturer’s written specifications.

d. kVp Accuracy

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

- \(\pm 2\) kVp of the indicated for \(< 30\) kVp,
- \(\pm 3\) kVp of the indicated for \(31-100\) kVp, and
- \(\pm 6\) kVp of the indicated for \(> 100\) kVp.

e. 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 \((X_1 - X_2) \leq 0.10(X_1 + X_2)\) where \(X_1\) and \(X_2\) are average mR/mAs values obtained at each of two consecutive tube current settings. A minimum of 4 measurements shall be made at each of the mA stations. The generator should be capable of maintaining the above linearity across all the available mA stations.

f. Half Value Layer (HVL)

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

<table>
<thead>
<tr>
<th>X-ray Tube Voltage</th>
<th>kVp</th>
<th>Measured Al (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed Operating Range</td>
<td>30</td>
<td>0.3</td>
</tr>
<tr>
<td>Below 50</td>
<td>40</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>49</td>
<td>0.5</td>
</tr>
<tr>
<td>Operative kVp</td>
<td>Minimum Total Filtration (Inherent Plus Added)</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Below 50</td>
<td>0.5 mm Al</td>
<td></td>
</tr>
<tr>
<td>50-70</td>
<td>1.5 mm Al</td>
<td></td>
</tr>
<tr>
<td>Above 70</td>
<td>2.5 mm Al</td>
<td></td>
</tr>
</tbody>
</table>

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

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, and when applicable the reason for holding the patient.

F. Repeat/Reject Analysis (App. D)

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. semiannually. It is important that the facility follow the procedures established to assure that the studies are carried out in the same manner each time.
G. Purchase Specifications and Acceptance Testing (App. E)

Before purchasing new equipment, the practitioner is encouraged to determine the desired performance specifications for any new equipment including film, screens, and chemistry.

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 system.

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.
BIBLIOGRAPHY


5. Checklist for Establishing a Diagnostic Radiology Quality Assurance Program. FDA 83-8219.


19. Radiation Protection for Medical and Allied Health Personnel, (NCRP), No. 48 (1976).


# LIST OF APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Quality Control Test Frequency</td>
<td>12</td>
</tr>
<tr>
<td>Appendix B – Processing QC</td>
<td>B-1 Initial Considerations in Beginning a QC Program</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>B-2 Setting-Up an Automatic Processor QC Program</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>B-3 Daily Automatic Processor QC</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>B-4 Setting-Up a Manual Processor QC Program</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>B-5 Daily Manual Processor QC</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>B-6 Darkroom Fog Test</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>B-7 Processor Problem Troubleshooting</td>
<td>27</td>
</tr>
<tr>
<td>Appendix C – Sample Test Procedures</td>
<td>C-1 Light Field/X-ray Field Alignment</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>C-2 PBL</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>C-3 Beam Misalignment</td>
<td>31</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Repeat-Reject Analysis</td>
<td>33</td>
</tr>
<tr>
<td>Appendix E</td>
<td>Performance Specifications</td>
<td>34</td>
</tr>
<tr>
<td>Appendix F – Policy and Procedures</td>
<td>F-1 Policy and Procedures for Patient Holding</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>F-2 Policy and Procedures for Pregnant Workers</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>F-3 Policy and Procedures for Use of Gonad Shielding</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>F-4 Policy and Procedures for Shielding Scoliosis Patients</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>F-5 Policy and Procedures for Pregnant Patients</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>F-6 Policy and Procedures for Personnel Monitoring</td>
<td>43</td>
</tr>
<tr>
<td>Appendix G</td>
<td>Radiation Output Measurements</td>
<td>44</td>
</tr>
<tr>
<td>Appendix H</td>
<td>Forms</td>
<td>45</td>
</tr>
</tbody>
</table>
APPENDIX A

Quality Control Test Frequency

Each Day of Operation

Equipment functioning
  Indicators and mechanical and safety checks

Processing
  Automatic processors – Speed, contrast, base + fog
  Manual processors – Daily temperature checks
    Every other day – speed, contrast, base + fog

Annual

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

Safelights/Darkroom Fog
Exposure Switch
Interlocks

Every Two Years

Film/Screen Contact
Timers
kVp
HVL
mA Linearity

On Installation of New Equipment/tube or Output Change

HVL and Average Patient Exposures
Radiation Protection surveys
Acceptance Testing
APPENDIX B-1

Initial Consideration in Beginning a QC Program
From “A Basic QA Program for Small Facilities”, FDA 83-8218

1. Select a Sensitometer

A processor quality assurance program must allow isolating processor variation from generator variation. For this reason it is necessary that the facility possess a sensitometer so that they may expose film by a means other than the x-ray unit.

A sensitometer is a device containing a light source and a timing mechanism designed to give precise, repeatable, and graded light exposures to the photographic film. The sensitometer is used to expose pieces of radiographic film, called sensitometric control strips or sensi strips, which are then processed to provide information for evaluation of processor operation.

Sensitometers are available commercially with a range of performance levels and special features and thus a range of prices. Reproducibility in exposure of the control strips is important but adequate reproducibility for a daily quality assurance program may be available from a lower priced sensitometer. Similarly, if you plan on using your sensitometer only for daily quality assurance you will not need the special features of the more expensive models.

A sensitometric step tablet is used in the sensitometer to give a range of exposures to the sensitometric control strip. The density range of the step tablet should be a least 3.0 and each step should be at least 3/8” wide. Most sensitometers supplied by manufacturers have tablets with 11 or 21 steps. Either number is acceptable for proper evaluation of the sensi strips. A 21 step tablet is preferred because it allows finer exposure increments between steps.

Care must be taken in the use of commercial sensitometers in daily quality assurance programs. The existence of 11 or 21 steps means that the density difference between adjacent steps are small. If the use of the sensitometer introduces variability in the densities produced, this added variability may obscure the processor variability that we are trying to detect. To minimize additional variability it is important that the sensitometric control strips be fed into the processor so that the less dense end of the exposed film will be leading. The strip should always move across the same location of the feed tray each time (extreme right side is recommended). Ignoring these precautions may introduce a surprising amount of variability in the density of the processed film. The time interval between exposure and processing also should be standardized.

The light emitted from the sensitometer must match the film/screen system you use, i.e. a blue light emitting source for film/screen systems with blue sensitivity and a green light for systems with green sensitivity.
2. Select a Densitometer

A densitometer is a device that measures the blackening or density of a developed radiographic film. To evaluate processor operation, sensitometric control strips are processed and their densities are measured with the densitometer. These measurements are compared to standard or past values depending on the type.

Read and follow the manufacturer’s instructions for your sensitometer and densitometer.

3. Obtain Control Film

Obtain control film which is produced with an emulsion from the same batch in quantity sufficient to last 2 to 4 months and assure that it is stored properly.

The emulsion is that part of the film sensitive to light and x-rays and is present in one or two layers on the film. Emulsions are made up in batches and despite rigorous manufacturer quality control efforts, the characteristics may vary from batch to batch. In general these variations are quite small so are not of concern when radiographs are made of patients. However, the goal of your quality assurance program should be to detect problems before they affect patients care. Thus the sensitometric-densitometric monitoring methods are more sensitive detectors of film variability than the normal film viewing methods. They may be sensitive enough to detect batch to batch differences not seen when films are viewed on the viewboxes.

It is important that these emulsion variations not be confused with or mask variations due to processor performance. Control film should be of the same brand and type normally used in the processor in which it will be processed. To save costs, use the smallest size film that will produce a complete image of your step tablet and will work in your processor, even if larger films are normally used for patients.

Another suggestion for the small facility that only processes films a few days a week is to remove 15-20 sheets of film and designate them the control film. Place them in a box clearly labeled “CONTROL FILM”. The rest of the film in the box can be used for patient studies. A full box of 100 sheets may last up to 6 months and could show a considerable change in characteristics before the last sheet was used.

X-ray film should be stored with care. As a minimum it is recommended that film be stored in a room maintained at 50 to 70 degrees F and 40 to 60 percent relative humidity. Low background radiation levels and freedom from chemical fumes should also be maintained. Freezing of film for storage is even more desirable. Freezing virtually stops deterioration caused by temperature or humidity although it cannot prevent fog caused by background radiation.

With either cold or frozen materials, care must be taken to allow the material to return to room temperature before use and to prevent the condensation of water vapor on the film. The best way to do this is to leave an unopened box of film on a shelf at room temperature for at least 8 hours. Once the container seal has been broken the film should not be refrozen.
When it is time to use new control film with a different emulsion batch number you will need to run five old and five new control film through the processor on the same day. The films should be marked to distinguish the new films from the old. The new and old films should be alternately run through the processor. Plot the old film on the charts and add the new values on the same chart so that they run simultaneously. The difference should be small between the two values, especially if the base + fog has not increased substantially. Average the five differences between the old and new film values for the new control film. Do this for the new speed, contrast, and base + fog values. Add and subtract by the limits to determine the upper and lower limits and mark on the control chart. Indicate on the chart the date of the change to the new control film. Adjust control limits up or down according to the average difference.

4. **Obtain an Accurate (+/- ½ degree F) Thermometer**

The most common cause of poor processor performance is failure to maintain the proper processing temperature. Temperature monitoring and correction will reduce the processing problems detected with sensitometer/densitometer monitoring. Should problems occur anyway, checking the temperature as a first step will often be all that is needed to locate the cause of the difficulty. An accurate thermometer is needed for this purpose.

*Never use a mercury thermometer in a radiographic darkroom.*

In general, any glass stemmed thermometer should be avoided because, even if filled with a material such as alcohol, removal of all the glass and liquid after the stem is broken will be difficult and possibly expensive. Mercury thermometers present a particular hazard because mercury is a contaminant even at a few parts per million. It is virtually impossible to remove all traces of mercury from a developing tank or a darkroom when a mercury thermometer breaks.

A digital thermometer is recommended, although a dial type with a 6 or 8 inch probe is an acceptable alternative. Commercially available digital thermometers provide superior accuracy and are relatively inexpensive. If a dial thermometer is used, the total range of dial readings should be as small as possible while covering the recommended processor operation range. Your readings should always be taken at the same location, one that has been chosen for reproducibility. Such locations must be found by trial and error through taking repeated readings at a number of points after the processor has stabilized. Use the locations with the most reproducible values for future monitoring.

Another precaution to follow is to always wipe the thermometer dry immediately after removing it from the developer or fixer tank. The thermometer should then be rinsed in running water before future use. This procedure will prevent the inadvertent transfer of fixer into developer.

5. **Check Sensitometer Calibration**

Once a year, or, after changing the battery, you need to check the sensitometer for consistency. Expose five control films and run through the processor. Read the first, last and middle steps for each of 10 strips. The variation among the same step values should not exceed 2%. If after
changing the battery, a change is noted greater than this level, you should modify the control
limits if the numbers are not in agreement.

6. Check Densitometer Calibration

Your densitometer should be calibrated when it leaves the manufacturer. However, the
manufacturer should also supply you with a calibrated step tablet covering a density range of 3.0
in density with density differences between steps of 0.3 or less. Upon receiving your
densitometer, carefully follow the manufacturer’s instructions for using this tablet to verify that
the densitometer is still calibrated over the range specified.

When reading any step tablet, the density should be measured in the center of the step. As you
check the calibration you should find that the values given for the tablet and those indicated by
the densitometer agree with +/-0.02 or +/-0.03, depending on the specifications of the
densitometer, for all steps of the tablet. If any of the steps are out of calibration, you should ask
the supplier to correct the defect.

The calibration of your densitometer should also be checked daily during use to guarantee that it
is not creating additional variability in your data. Again the calibrated wedge supplied by the
manufacturer should be used for this. Some facilities prefer not to use the manufacturer’s wedge
for these checks in order to minimize the chances of damage or loss. As an alternative, they
However, if reasonable care is taken in the use and storage of the manufacturer’s step wedge,
production of a secondary standard should not be necessary.

7. Set Processor at Manufacturer’s Optimum Conditions

Make sure that your processor is set at the film manufacturer’s optimum conditions for the film-
developer combination that you are using. If the manufacturer does not supply recommended
processing conditions for your film developer combination, you will need to optimize processing
conditions yourself.

It is generally most desirable from a quality assurance standpoint to use the chemistry
recommended by the manufacturer of your film or at least a chemistry for which the
manufacturer can provide recommended processing conditions. In such a case your only concern
is to make sure the processor is operating as close as possible to the temperature and speed
recommended by the manufacturer. However, you may be using a chemistry for which the
manufacturer of your film cannot provide recommended processing conditions. In such a case
you should seriously consider going through the process of optimizing your processor as
described in Sections 4.3 and 4.4 of reference 13.
APPENDIX B-2

Setting-Up an Automatic Processor QC Program
Adapted from Gray, Winkler, Stears and Frank (16)

Purpose

To determine the operating levels for the automatic processor.

Equipment Needed

<table>
<thead>
<tr>
<th>Sensitometer</th>
<th>Densitometer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stopwatch</td>
<td>Film</td>
</tr>
<tr>
<td>Fresh Chemistry</td>
<td>Digital or metal-stemmed dial thermometer</td>
</tr>
</tbody>
</table>

Procedure

1. Drain the developer and fixer tanks in the processor and flush the tanks and racks with fresh water. (Note: Do not use systems cleaner at this time. Even minute traces of the strong acid can contaminate the chemistry.)

2. Replace the developer re-circulation filter with a new filter and assure that the processor is functioning normally.

3. Drain and flush the replenisher tanks and hoses with fresh water.

4. Carefully mix fresh developer, replenisher and fixer.

5. Refill the replenisher tanks, operating the replenisher pumps temporarily to assure that all fresh water is flushed out of the replenisher lines and to assure that the replenisher pumps are functioning properly.

6. Flush the processor fixer tank again with fresh water.

7. Fill the fixer tanks in the processor with fresh fixer and replace the fixer rack.

8. Again flush the developer tank.

9. Fill the developer tank with fresh developer-replenisher and add the correct amount of starter as noted in the manufacturer’s instructions.

10. Carefully replace the developer rack, crossover racks, etc.

11. Allow the processor to operate for 30 minutes.
12. Check the developer temperature, fixer temperature, and wash water temperature. The developer temperature should be within 0.5 degrees Fahrenheit of that recommended by the manufacturer. Fixer and wash temperatures can vary up to +/-2F.

13. Check the replenishment rates and the time it takes a film to pass through the processor (the time it takes from when the leading edge enters the processor until the leading edge exits the processor).

14. Allow the processor to be used until it is stable and the films look good.

15. Using the sensitometer, expose a sheet of control film. Expose one side, turn over the film and expose the other end of the other side.

16. Process the film using the same side of the feed tray for each film.

17. Zero and check the calibration of the densitometer. This means using the accompanying check calibration strip and reading each step. Take several readings across each step and average the readings. The readout should be within a few tenths of the average.

**Determining Control Limits**

18. Read the densities on the two strips. Be sure to read the densities in the center of each strip, not near the edges. (Check the zero and calibration of the densitometer after reading each strip.) Mark the value next to the step. Average the two measurements for each step of the tablet.

19. Take three readings of the clear area of the film and average the values. This is the base + fog level of the film. Record the base + fog on the control chart.

20. Identify the step with an optical density closest to 1.2. This step represents a medium density measurement of 1.0 plus base + fog. Record this value on the control chart as the speed step or medium density. There is a +/- variation of .15 OD for the control range for a daily use processor. There is a +/- variation of .20 OD for occasional use processors.

21. Identify the step with the density closest to but not exceeding 2.20. Next select the step with the density closest to 0.5 but not lower than 0.45. Subtract the smaller of the two numbers from the larger. This difference is the density difference or contrast step. Record this value on the control chart as the contrast or density step.

22. Repeat steps 11 through 21 for the next four days. Use the average of the measurements made over the five days to establish the control limits.
Establishing Upper and Lower Level Control Limits

23. The upper and lower control limits are determined through some math calculations. Utilizing the numbers identified as the speed and contrast steps from the previous section, calculations can be made to set up parameters that will allow for processor variability.

24. The range in variation is +/- .15 OD for automatic processors and +/- .20 OD for occasional use processors.

Add 0.15 to the value determined to be the speed step to find the upper control limit. Subtract 0.15 from the value to find the lower limit. The same process is used to determine the upper and lower limits for the contrast step.

An example is as follows: the value for the speed step is determined to be 1.21. To determine the upper control limit for the speed step, 1.21 + 0.15 = 1.36. 1.36 is recorded as the upper control for the speed step. To determine the lower control limit, 1.21 - 0.15 = 1.06 is recorded as the lower control limit for the speed step. Occasional use processors would add 0.20 to determine the upper limit and subtract 0.20 to identify the lower control limit.

25. Average the base + fog level for the five films. The base + fog level must not exceed this control limit by more than 0.03 OD.
APPENDIX B-3

Daily Automatic Processor Quality Control

Purpose

To stabilize the processing of films. The processor is the piece of equipment in your facility that is most susceptible to variation. The quality of its performance can fluctuate greatly from day to day and even during a single day. Because of this variability, the frequency of quality assurance actions directed at the processor must be higher than for other equipment if they are to be effective.

Equipment Needed

Sensitometer
Densitometer
Digital Thermometer or metal-stemmed dial thermometer
Control Film

Procedure

1. Turn on the processor and follow the manufacturer’s start-up procedures.

2. Allow sufficient time for the temperature to stabilize.

3. Check solution temperatures, replenishment rates, water temperature, flow rates, and dryer temperature to make sure they are at the manufacturer’s recommended levels. Ideally your unit will have built-in thermometers and flow meters to facilitate this.

4. Process clean-up sheets (exposed but unprocessed film) to remove any residue from the racks and to check for processor scratches.

5. Expose a sensitometric control strip (one on each side of dual emulsion films) and process with the light density end of the wedge leading to avoid variability because of direction factor. In addition, care must be taken to assure that the control strip is processed at the same location on the processor feed shelf (left-to-right) each time. For consistency the strips should always be processed at the same time interval after exposure as step 16 in Appendix B-2.

6. The density of the base + fog, contrast, and speed index are read and plotted on the control charts.

The control strip should be exposed before any patient film is run in the morning but after the processor is fully operational. This will determine if the chemistry was contaminated or degraded during the previous day before the new day’s workload begins. This will also avoid the possibility that any film processed just prior to the control strip will have upset the
chemical equilibrium. It is also recommended that the strips be processed approximately 1 hour after the machine has been brought up to temperature, if there is this much time before the patient work begins, to guarantee temperature stability has been achieved.

By-products of development, especially bromide ions, diffuse out of the film and can retard development particularly if processor agitation is suboptimal. These products will flow over the film affecting the trailing portions of the film. The less exposed end of the strip is fed into the processor first to minimize this effect. Processors exhibit differences in agitation and temperature from one side of the development tank to the other. Film should always be processed in one location to minimize this problem.

In summary the most important thing is that the strips be exposed and processed in the same way each time. This will lessen the chance that variability in the data will result from causes other than variability in the performance of the processor itself.
Setting-Up a Manual Processor Quality Control Program

Purpose

To determine operating levels for manual processing.

Equipment Needed

- Sensitometer
- Densitometer
- Film
- Fresh Chemistry
- Stopwatch
- Digital or Metal-Stemmed Thermometer

Procedure for Mixing Chemistry

Processing solutions should be mixed according to the directions on the labels. Mixing vessels should be made of stainless steel, enamelware, glass, hard rubber, plastic or glazed earthen ware. Aluminum, galvanized iron, tin, copper and zinc will contaminate solutions.

Agitators, made of hard rubber, stainless steel, or other material that does not absorb or react with processing solutions are recommended. Separate agitators should be used for the developer and fixer.

Manufacturer’s provide chemistry as multi-part liquid concentrates or as a single solution package. It is imperative that the manufacturer’s instructions be followed in the preparation of processing solutions. Your technical sales representative is your best information resource when seeking information about processing especially when different manufacturers products are being combined to complete a system.

Procedure for Setting Up Processor Tanks

1. Drain developer and fixer tanks. Flush the tanks with fresh water and drain again.
2. Refill the developer tank with fresh developer.
3. Fill the fixer tank with fresh fixer.
4. Drain the water rinse bath. Clean bath with fresh water and drain tank.
5. Refill the water rinse bath with fresh water.
6. Check the temperatures in the developer, fixer, and rinse water. Chemistry temperatures should be within 1.0 degree F of those recommended by the manufacturer.
7. Expose a sheet of control film using the sensitometer. Expose one side, turn the film over and expose the other side of the film.


9. Zero and check the calibration of the densitometer utilizing the accompanying check calibration strip. Take several readings across each step and average the readings. The readout should be within a few tenths of the average. Mark the value next to the strip.

10. Read the densities on the two strips in the center of each strip not near the edges. (Check the zero and calibration of the densitometer after reading each strip.) Mark the value next to each strip. Average the two measurements for the same step of the tablet.

11. Take three readings of the clear area of the film and average these values. This is the base + fog level of the film. Record the base + fog on the control chart.

12. Identify the step on the sensi strip with the optical density closest to 1.2. This step represents a medium density measurement of 1.0 plus base + fog. Record this value on the control chart as the speed step or medium density. There is a +/- .15 OD variation for the control range for daily processors. There is a +/- .20 OD variation for the control range for occasional use processors.

13. Identify the step with the density closest to but not exceeding 2.20. Next select the step with the density closest to 0.5 but not less than 0.45. Subtract the smaller number from the larger. The difference is the density difference or contrast step. Record this value on the control chart as the contrast or density step. There is a +/- .15 OD variation for the control range for daily processors. There is a +/- .20 OD variation for the control range for occasional use processors.

14. Repeat steps 7 through 13 for the next four days. Use the average of the measurements made over the five days to establish the control limits.

15. Average the base + fog level for the five films. The base + fog must not exceed this control limit by more than 0.03 OD.
APPENDIX B-5

Daily Manual Processing Quality Control
From DuPont Product & Processing Guide for the Professional Office

Purpose
To stabilize the processing of films. Processing is the factor that is most susceptible to variation. Because of this variability, the quality assurance actions directed to processing must be higher than that for other equipment.

Equipment Needed
- Sensitometer
- Time/Temperature chart from Manufacturer
- Control Film
- Digital or metal-stemmed dial thermometer
- Densitometer

Procedure
1. Follow the manufacturer’s start-up procedures.
2. Check the solution temperatures for the developer, fixer and rinse.
3. Expose a sensi strip (once on each side).
4. Process the sensi strip. Load the hanger by starting at bottom fixed clips. Make sure hands are clean and dry. The top spring clips pull the film taut.
5. **Consult the developer time/temperature chart to determine processing time.**
6. Place film in developer, start timer, agitate vigorously every 30 seconds for the duration of the development. An example is 5 minutes @ 68 degrees F.
7. Drain film over water, place in water rinse bath and vigorously agitate for about 10 seconds.
8. Drain film. Start timer and place film in fixer solution with vigorous agitation immediately for 10 seconds and then at the end.
9. Drain film and place in water rinse bath for 30-60 seconds with initial agitation. Move films in this bath toward the right so they rinse in the cleanest water. Films should rinse for 10-30 minutes.
10. Drain films and place in the dryer.
11. Record the measurements for base + fog, medium density, and density difference on control charts and compare to upper and lower control limits.

In summary, the most important thing is that the strips be processed the same way every time. This will lessen the variability in the data.
APPENDIX B-6

Darkroom Fog Check

Purpose

To assure that the safelights and other potential sources of "unsafe" light will not fog the film being handled in the darkroom.

Equipment Needed

<table>
<thead>
<tr>
<th>Film</th>
<th>Sensitometer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stopwatch</td>
<td>Densitometer</td>
</tr>
<tr>
<td>Two pieces of black, opaque papers each as long as the film to be used and one-half the film width.</td>
<td></td>
</tr>
</tbody>
</table>

Procedure

1. Turn off all safelights and any other type of lights in the darkroom. Check the darkroom for any source of light that may be getting into the room. Turn off any indicator lights that may be on equipment in the darkroom.

2. In complete darkness, open a new box of film, and remove a sheet.

3. Expose each of the long edges of the film using the sensitometer.

4. Place the exposed film on the workbench closest to the safelight in the area where film is routinely handled and has the highest probability of safelight exposure. (If there appears to be another area in the darkroom that contributes to darkroom fog, you should evaluate that area also).

5. Place the black opaque paper on the film so that it completely covers one half of the film including one of the sensitized edges.

6. Turn on the safelights and any indicator lights.

7. Expose the uncovered half of the film to normal safelight conditions for two minutes. Make sure that you are not accidentally shielding the film from other potential fog sources such as safelights or digital light sources.

8. After the two minutes have elapsed, quickly remove the film from the black paper, place the film on the tray and process the film.

9. Choose a step on the covered side of the film that reads approximately 1.0 O.D. Read the same number step on the side of the film exposed to darkroom conditions. The density difference should be less than 0.05 O.D.
10. Fogging can either be attributed to improper bulb wattage, close safelight positioning, too many safelights, wrong safelight filter for the film processed or any combination of factors.
APPENDIX B-7

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 +/- ½ 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:

\[
\frac{W_2}{D_2} = \frac{W_1}{D_1}
\]

W2 – width of x-ray field at film plane in bucky.
W1 – measured width of the x-ray field on the tabletop 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:

\[
\frac{L_2}{D_2} = \frac{L_1}{D_1}
\]

L2 – measured x-ray field length on tabletop film.
L1 – 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 ensure 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 x 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 x 100% = 43%.

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 stations
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.
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:

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


[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

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

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: A Basic Quality Assurance Program for Small Diagnostic Radiology Facilities. FDA 83-8210

### ACTIONS ON PROCESSOR

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Actions (Circle One – See Key)</th>
<th>Previous Setting</th>
<th>New Setting</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL  CC  CD  CF  RI  RL  MD  MF  TD  TW  MR  OT</td>
<td>_____</td>
<td>_____</td>
<td>_______________________________</td>
</tr>
</tbody>
</table>

Key:
- CL – Cleaned
- RI – Increased Replenishment Rate
- TD – Developer Temperature Adjust.
- CC – Total Chemistry Change
- RL – Lowered Replenishment Rate
- TW – Water Temperature Adjust.
- CD – Changed Developer
- MD – Mixed New Developer Replenh.
- MR – Mechanical Repair
- CF – Changed Fixer
- MF – Mixed New Fixer Replenh.
- OT – Other (Comment)

**Figure 6 Processor maintenance log**
| Visual and Manual Quality Control Checks |

<table>
<thead>
<tr>
<th>Building:</th>
<th>Section:</th>
<th>Room #:</th>
<th>Tube:</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERHEAD TUBE CRANE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TFD Indicator or marks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angulation indicator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locks (all)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perpendicularity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field light</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bucky center light</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High tension cable/other cables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overhead crane movement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bucky lock</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cassette lock</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Float and power top switches</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measuring caliper</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step stool</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angulation indicator/stop</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot board and shoulder braces</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TABLE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand switch placement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Window</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panel switches/lights/meters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technique charts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overload protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL BOOTH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locks (all)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power assist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motion smoothness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switches/lights/meters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression device/spoon</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopic monitor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopic grid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopic timer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopic drapes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Park position interrupt</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoro shutters visible – high</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoro shutters visible – low</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonad shield/aprons/gloves</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bucky slot cover</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pass = √
Fail = F
Does not apply – NA

3/15/2004
<table>
<thead>
<tr>
<th>Cause</th>
<th>Number of Films</th>
<th>Percentage Of Rejects</th>
<th>Percentage Of Repeats</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Positioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Patient Motion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Light Films</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Dark Films</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Clear Film</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Black Film</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Tomo Scouts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Static</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Fog – Darkroom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Fog – Cassettes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Mechanical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Q.C.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Miscellaneous (?)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Good Films</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Waste (1-4)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Rejects (All except 5 and 12)</td>
<td></td>
</tr>
<tr>
<td>Total Repeats (1-4, 6, 8-11, 14)</td>
<td></td>
</tr>
<tr>
<td>Total Film Used</td>
<td></td>
</tr>
</tbody>
</table>