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, osteopathic 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 I of Title 10 (Health) of the Official Code of 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 Program

A. Radiation Safety/Quality Assurance Responsibility

The physician, osteopath 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.

3. Radiation Output Measurements for Common X-ray Examinations (App. G)

   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 (Appendices 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 at least two years.

5. QC Records for Test Equipment

   Records shall be maintained and available for review for QC test equipment requiring calibration

6. Radiation Safety Policies and Procedures (Appendix F)

   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 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 0.25 O.D. and should not exceed 0.20 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 (Appendix C-1)

Total misalignment 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) (Appendix C-2)

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

(3) X-Ray Field/Image Receptor Alignment (Appendix 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 (Appendix B-6)

An x-ray 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 Reproducibility (Includes Automatic Exposure Control)

The coefficient of variation of radiation exposures shall be no greater than 0.05, where x is the average of the output of the time readings, and s is the standard deviation:

$$\frac{s}{x} \leq 0.05$$

One method to determine if units are in compliance is to show in field testing that the O.D. of four exposures does not vary by more than 10%, when measured on a film, using a step wedge or similar device as an attenuator and a specific time, kVp, and mA.

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:

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.

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.

This is $(X1-X2) < 0.10(X1+X2)$ where X1 and X2 are average mR/mAs values obtained at each of two consecutive tube current settings. A minimum of 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:

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 noncertified 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

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 (Appendix 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 (Appendix 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 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

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 field 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 at 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. 21 steps is preferred, allowing 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 and so that the strip always moves 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, their densities are measured with the densitometer, and 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 in quantity sufficient to last 2 to 4 months which is produced with an emulsion from the same batch 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 patient 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 which 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; it 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 returned to a cool or freezing condition.

When it is time to use new control film with a different emulsion batch number you will need to run the old and new control film together for three days. Continue to 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. After three days with the processor under control average the three 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 (+/- 1/2 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 which 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 and using 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 construct secondary standards using the procedure described on pages 17-19 of reference 13. 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

Sensitometer	Densitometer
Stopwatch	Film
Fresh Chemistry	Digital or metal-stemmed dial thermometer

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 recirculation 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 those recommended by the manufacturer. Fixer and wash temperatures can vary up to +/- 2 F.

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 three sheets 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 decimal points of the average.

Determining Control Limits

18. Read the densities on the six 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 all six 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.

20. Record the base + fog on the control chart. The value should not exceed 0.20 Optical Density (OD) and shall not exceed 0.25 OD.

21. 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 O.D. for the control range for a daily use processor. There is a +/- variation of .20 O.D. for occasional use processors.

22. 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.

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 O.D. for automatic processors and +/- .20 O.D. 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 add 0.15= 1.36. 1.36 is recorded as the upper control for the speed step. To determine the lower control limit 1.21 subtract 0.15 = 1.06. 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.

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 and 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 take 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 allow determining if the chemistry was contaminated or degraded during the previous day before the new days work load begins. This will also avoid the possibility that any film processed just prior to the control strip will have upset the chemical equilibrium. On the other hand it is 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 suboptimum. 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 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.

APPENDIX B-4

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 or of enamelware, glass, hard rubber, plastic, or glazed earthenware. 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 three sheets of control film using the sensitometer. Expose one side, turn the film over and expose the other side of the film.

8. Process each of the films in an identical manner.

9. Zero and check the calibration of the densitometer utilizing 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 decimal points of the average. Mark the value next to the strip.

10. Read the densities on the six 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 each of the six measurements for the same step of the six tablets.

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

12. Record the base + fog on the control chart. The value should not exceed 0.20 Optical Density (O.D.)

13. 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 O.D. variation for the control range for daily processors. There is a +/- 20 O.D. variation for the control range for occasional use processors.

14. 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.

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 — Densitometer
Control Film — Digital or metal-stemmed dial thermometer

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

Film
Densitometer
Stopwatch
Cassette
Two pieces of black, opaque paper each as long as the film to be used and one-half of the film width.

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 load a cassette.

3. In a radiographic room, expose the film with a technique where the density measured on the film would be approximately 1.0 O.D.

4. In total darkness, place the exposed cassette 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. Take the film and place it so that the black, opaque paper completely covers one-half of the exposed film.

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. Measure the optical density in adjacent areas on each side of the film. The density differnece should be less than 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.