5. PROCESSING QUALITY CONTROL

Experience at several facilities has shown that many image quality problems originate during the processing of the radiographic film. For example, a study conducted at the Baltimore Public Health Service hospital revealed that 30 percent of all retakes due to improper film density were caused by processor variation. Similarly fogging of film due to excessive light in the darkroom was seen in 73 percent of 900 darkrooms surveyed in 19 states. Fortunately the processing and darkroom problems can be controlled with a relatively small investment in equipment and time. Since this small investment can lead to a major impact on image quality we encourage facilities to consider beginning their quality assurance program in this area.

5.1 PROCESSOR QUALITY ASSURANCE

The following processor quality assurance program has been excerpted from Volumes I and II of "Photographic Quality Assurance in Diagnostic Radiology, Nuclear Medicine, and Radiation Therapy" by Joel E. Gray (on the following pages, these publications are referred to as Gray-I and Gray-II). Details on the availability of this publication are given with the references.

5.1.1 Initiation of a Quality Assurance Program

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 posess 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.

   On the other hand for sensitometric evaluations of photographic materials to determine which film is the best for a particular application, the sensitometer must match the conditions under which the film will be used in the department as closely as possible. The sensitometer must be capable of reproducing the exposure time for the radiographic screens to be used with the film. In general smaller facilities would not need to carry out such evaluations but could rely upon findings at larger research centers. A relatively inexpensive sensitometer may be adequate for your needs.

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. A densitometer may measure the density electronically or visually.

Visual densitometers are the least expensive as they make use of the human eye to compare the density of a known value to.that of a sample strip. However, there are problems with eye fatigue, reading densities above 2.0, and if more than one individual is doing the reading, repeatibility with these densitometers.

These problems are minimized with electronic densitometers but such electronic densitometers are more expensive and offer additional features that may or may not be needed. Nonetheless electronic densitometers are preferable in all situations and are essential if you are planning sensitometric evaluations of photographic materials, reading large numbers of films or will have several staff members involved in the reading.

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

3. Select steps on 11 or 21 step wedge

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. This number is essential for sensitometric evaluation of photographic materials but for daily quality assurance monitoring, it is necessary to measure only the density of the base-plus-fog (B + F) region plus that of the three steps which are about 0.25, 1.00, and 2.00 above the B + F level of the film. The B + F level is the density of the film which has received no radiation or light exposure and has been processed normally. It is used to monitor the extent to which the film is exposed by other than diagnostic radiation, such as extraneous light in the darkroom. If for example the B + F level for a particular film is 0.25, the three steps used would be those with densities of about 0.50, 1.25, and 2.25. The B + F + 1.00 step will be used as the Medium Density or MD step. The difference between the other two steps, which normally will be 1.75, will be used as the density difference or DD.

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 differences 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 will introduce a surprising amount of variability in the density of the processed film.

4. Obtain control film

Obtain a sufficient quantity of control film produced with photographic emulsion from the same batch and assure that it is stored properly.

The photographic emulsion is the 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. For this reason when ordering film for use with your sensitometer-densitometer in quality assurance monitoring, be sure you order enough film to last for 6 months to 1 year so that the same emulsion batch will be used during this period. This control film should be of the same brand and type normally used in the processors in which it will be processed. To save costs, it may be 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.

You may experience difficulty at first in ordering a sufficient supply of film with the same emulsion number. You should work with your technical representative on this. Each time you change control film from one emulsion batch to another, you must obtain a conversion factor which will allow you to convert the data taken with one emulsion batch to be equivalent with the data from the other batch. This is necessary in order to be able to compare data taken over a period of time. To save time you should try to avoid having to do this more often than once every 6 months to a year.

Once you have obtained your supply of control film, you must store it carefully so that there is no deterioration. The last sheet used should have the same properties as the first one used 6 to 12 months earlier.

As a minimum it is recommended that the control film, or for that matter all film, be stored in a room maintained at 50 to 70 °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 materials 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. Care should be taken not to warm more than a weeks supply of control film at a time to prevent excessive deterioration.

From time to time you will have to change control film either because your previous supply is exhausted or because the facility is using a new kind of film. The procedures for this are discussed in subsection 5.1.7.

5. Obtain an accurate (± 1/2 °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.

<u>Never use a mercury thermometer in a radiographic darkroom.</u>

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 if 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, and 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 still 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 on 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 inadvertant transfer of developer into fixer.

6. Set up log book

This log would not be used to record the measurements taken by the sensitometer, (that will be discussed later) but rather the use time of the sensitometer. As shown in the example below, this log can be kept rather simple. Its primary purpose is to keep a running total of the hours of use in order that you may be aware of when the light source is approaching the end of its life. This is especially important for sensitometers with tungsten lamps which should be replaced after the number of hours recommended by the manufacturer. Continued use of a lamp beyond its recommended lifetime is false economy as you run the risk of deterioration in the lamp affecting your data and unexpected burnouts at inconvenient times.

Model:__________ Bulb No.:__________ Bulb Current:__________

Date	Initials	Time On	Time Off	Cumulative Time

Figure 4. Sensitometer usage log.

7. Check densitometer calibration

Your electronic 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 wedge and those indicated by the densitometer agree with ±0.02 or ±0.03, depending upon the specifications of the densitometer, for all steps of the wedge. 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 routine checks in order to minimize the chances of damage or loss. As an alternative, they construct secondary standards using the procedure described by on pages 17-19 of Gray-I. 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.

8. Construct and maintain a densitometer control chart

The results of the electronic densitometer calibration checks should be recorded on the densitometer control chart and the data evaluated periodically to determine if the densitometer is adding excessive variation to your readings. An example control chart is shown in Figure 5. To maintain it the following steps should be carried out every day before the densitometer is used for radiographic quality assurance work.

a. Turn on the densitometer power supply and light source and allow it to warm up for at least the minimum period specified by the manufacturer.

b. Zero the densitometer according to the manufacturer's instructions.

c. Read the center of the three steps on the manufacturer's calibration step tablet which are closest in density to the monitoring steps selected in C. above. Record the density values on the densitometer control sheet.

d. If any of these calibration readings vary more than ±0.02 or ±0.03 (according to manufacturer's specifications) from the original values found in 7 above, recheck the readings.

e. If any of the densities measured using the manufacturer's calibration step tablet densities vary more than ± 0.02 or ± 0.03 (according to manufacturer's specifications) from the correct value, your densitometer is in need of calibration. Consult the manufacturer or his representative. (Note any discrepancies and the date on your densitometer control chart.)

9. Use of visual densitometer

There are no quality assurance procedures for the visual densitometer equivalent to those for the electronic densitometers. This is another reason why electronic densitometers are preferable. However, if a visual densitometer is used, pages 21-22 of Gray-I. should be consulted for a description of ways to minimize errors.

10. Test darkroom for light fog

This will be discussed in Subchapter 5.2.

Instrument:________________ Model:________________ Serial #______

Calibration: ________________ Standard Wedge # ____________________

0.06

High

− 0.06

0.06

Med.

− 0.06

0.06

Low

− 0.06

Initials & Date

Figure 5. Densitometer control sheet.

11. Set processor at manufacturer's optimum conditions

Make sure that your processor is set at the 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 should 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 in this step 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 Gray-I. Optimization should be considered because if the processor is operated at nonoptimal conditions, it is possible that the techniques of the radiographers have been adjusted to compensate for this. Such adjustments often lead to unnecessary exposure being given and may not be entirely successful in counteracting the bad effects of sub-optimal processing on image quality. On the other hand you should be aware that if techniques have been adjusted to fit your present suboptimal processing condition, you will probably have to adjust the generator techniques again if you optimize your processor. Otherwise you may find yourself in the curious position of having your processor working better than ever before yet be receiving complaints about film quality because the old compensating techniques are no longer the desirable ones.

12. Establish image quality standards

If you have not already done so, establish your Standards for Image Quality for the processor.

There will always be some variation in equipment performance no matter how good your quality assurance program is. Thus it is important to have established Standards for Image Quality to help the staff determine when the variation detected by their monitoring is serious enough to affect the quality of the image.

In the case of the processor, if you follow the procedures recommended below under Daily Quality Assurance Procedures, you will be processing daily a sensitometric strip exposed in a sensitometer. Using a densitometer, you will obtain three values for each strip: the density of unexposed film (Base plus Fog or B + F) the density of a medium density step (MD) and the difference in density (DD) between a high and low density step. With automatic processing and a sensitometer and densitometer operated and calibrated as discussed above, the density representing (B + F) should be with ±.05 optical density units of the expected value while the values of MD and DD should be within ±0.10 of the expected values. In the case of hand processing, it might be necessary to increase your control limits to ±0.15 although with practice and care ±0.10 is achievable even with hand processing.

If the measured values are within these limits, the operation of the processor can be considered satisfactory. Thus, these limits can be used as your Standards for Image Quality. If your measured values consistently fall outside of these standards, some corrective action is needed to improve processor performance as discussed below.

13. Construct processor maintenance logs

Processor maintenance logs are used to maintain a permanent record of preventive maintenance, corrective maintenance, and cleaning of the processor. An example is shown in Figure 6. The log should be mounted beside the processor in a clear acetate jacket so that the information is clearly visible as a reminder of the actions that must be carried out. Such a log is particularly useful in allowing quick checks to see if things have been done and in tracing changes in processing conditions that may take days or weeks to become apparent.

Each action should be dated and initialed. If difficulties are detected during monitoring the processor maintenance log may contain hints as to where to begin looking for the solution. For example, if it has been some time since the racks were cleaned or the developer filter changed, these may be the source of your difficulty. If problems appear immediately after developer or fixer replenisher tank was filled, the problem may be an improperly mixed batch. In general, the processor maintenance log will be quite useful, not only as a check on determining that things get done, but also as an analytical tool to locate problems.

14. Construct processing control charts

The processing control chart is a graphical method of presenting the data collected by monitoring over a period of time. This allows examination not only of the situation on a particular day but of the trends in your processor performance with time. Such trends may be more useful as indicators of pending problems and their sources than the daily values.

A sample control chart is shown in Figure 7. As can be seen space is provided to record B + F, MD and DD readings taken over a period of a month. It is suggested that horizontal lines showing the control values used as Standards for Image Quality (± 0.10, ± 0.05, or whatever values you have chosen) be drawn in with red ink so that it is immediately apparent when the variation exceeds the acceptable values. A separate control chart should be used for each processor. Other suggestions include:

a. Fill in the chart as soon as possible after the data is taken to avoid the possibility of forgetting or losing it.

b. Connect the data points with straight lines

c. If your measured data indicates the processor is exceeding the control limits, plot it anyway and circle all three points even if only one point is out of control. Then after the situation has been corrected, as described under Daily Quality Assurance Procedures, plot the data points which correspond to the corrected levels and indicate the changes in the Remarks section.

d. Indicate chemistry changes by a double vertical line on the chart.

e. Examine the control chart daily for trends or indications of problems. (The analysis of the control charts to identify problems is discussed in more detail in Appendix B.)

ACTIONS ON PROCESSOR

Date	Time	Actions (Circle One – See Key)	Previous Setting	New Setting	Comment
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			
	am pm	CL CC CD CF RI RL MD MF TD TW MR OT			

KEY:

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

Figure 6. Processor maintenance log.

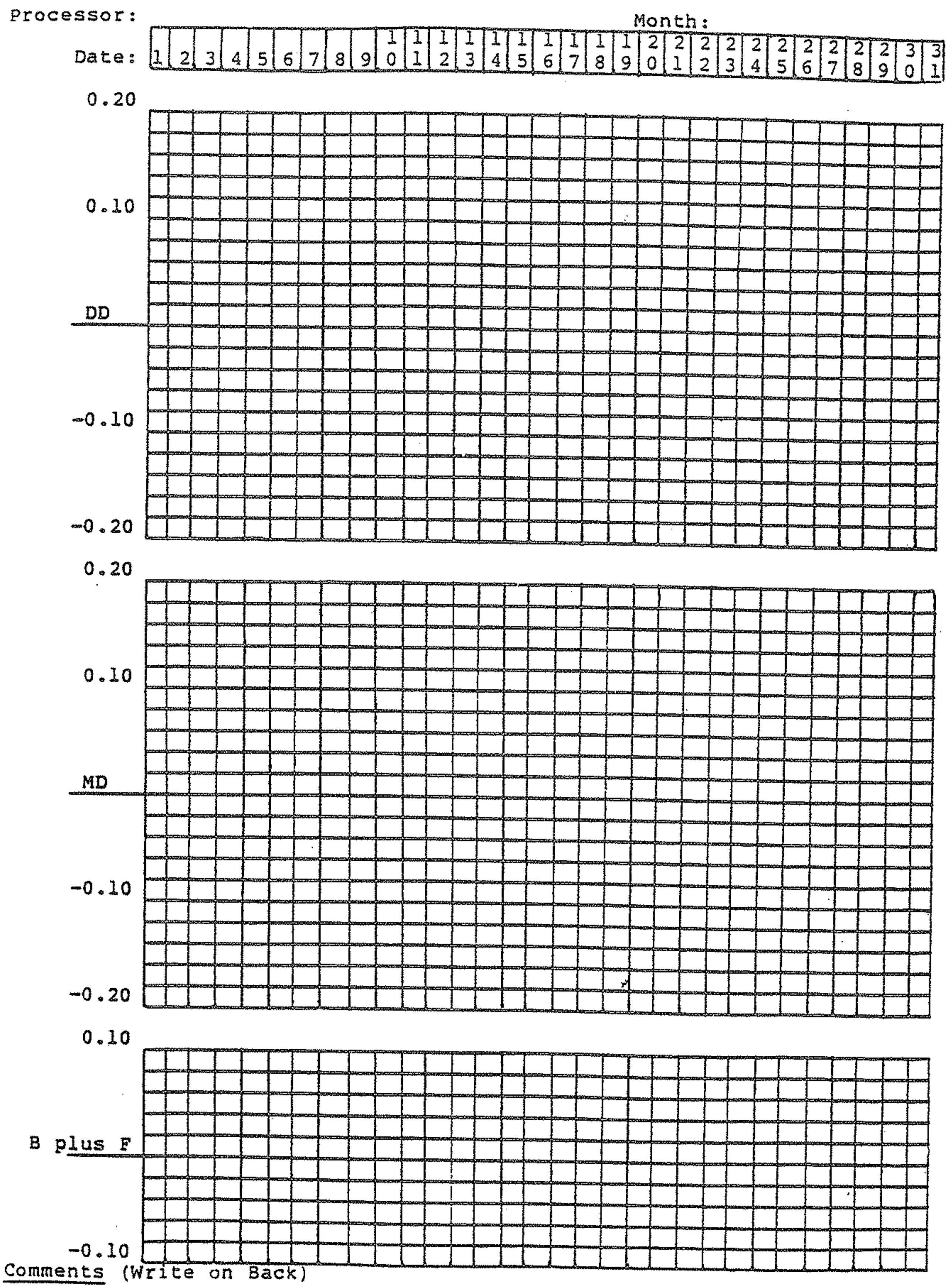

Figure 7. X-ray processing control chart.

5.1.2 Daily Procedures

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 or 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. There are a number of actions that in general should be taken daily. These are:

1. Turn on all processors 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) for each processor and process with the light density end of the wedge leading to avoid variability because of the 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 roughly the same time interval after exposure.

   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 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. On the other hand it is recommended that the strips be processed approximately 1 hour after the machines have been brought up to temperature, if there is this much time before the patient work begins, to guarantee temperature stability has been achieved.

   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.

6. The density of the three steps selected for use under Step 3 of 5.1.1 plus the B + F level should be read (with each step being averaged from the two exposures on the dual emulsion film). The B + F, Medium Density, and Density Difference values should be plotted.

   To illustrate the plotting of this data, assume the initial measured values of the density for a processed strip were 0.21 for B + F, and 0.46, 1.21, and 2.22. for the three selected steps. You would thus use 0.21, 1.21, and 1.76 (2.22 - 0.46) for your B + F, MD, DD values respectively. These values would be recorded on the midlines of the three graphs of the control chart as shown in Figure 8 and also as dots in the middle of the Day 1 columns. On the second day, these values might be 0.23, 1.23, and 1.77. These values would be plotted in the Day 2 column and the dots connected by straight lines. As you can see, the processor performance has varied slightly from Day 1 to Day 2 but the variation is within the Standards for Image Quality (shown by dashed horizontal lines) which have been selected. As time passes the amount of variation increases in our example and occasionally the measured value of one or more of the quantities falls outside the control limits as indicated with the circled dots (the dots for all three values are circled even if only one falls outside the limits). However, through the corrective actions discussed below it is usually possible to bring the processor performance back within limits as indicated by the readings on a new strip. The dots from these new readings are plotted and are used to extend the graph while a notation is made of the action taken under remarks.

7. If all three data points fall between the Standards for Image Quality, and no trend is apparent, the processor is in control and needs no further attention until Step 12 at the end of the day. If one or more data points fall on, or exceed the standards, then the following steps should be followed.

8. Process and measure another pair of control strips (one on each side of a dual emulsion film) to assure that the apparent change was not because of experimental error or random variability.

9. If the change is real, then the problem must be located. Examples of the use of monitoring data to determine the source of the problem are discussed in Appendix B. The following sequence of checks also can be used to locate problems.

   The rack cleaning, replenishment dates, and processor maintenance dates recorded in the processor maintenance log should be checked first. If contamination has occurred or a batch of replenisher was improperly mixed, these effects should show up within a day or two of the log dates. Thus these factors can probably be eliminated as a source of the problem if the dates were some time in the past. However, even if the dates are such as to make one or more of these problems a possibility, you should still complete the checks below. Correction of these problems requires a major and somewhat expensive effort and should not be undertaken unless you have eliminated the other causes first.

   Check the developer and water temperatures next since improper operating temperatures are perhaps the most common cause of poor processing.

   Check replenishment rates, water flow, transport time, recirculation pump, and filter condition last.

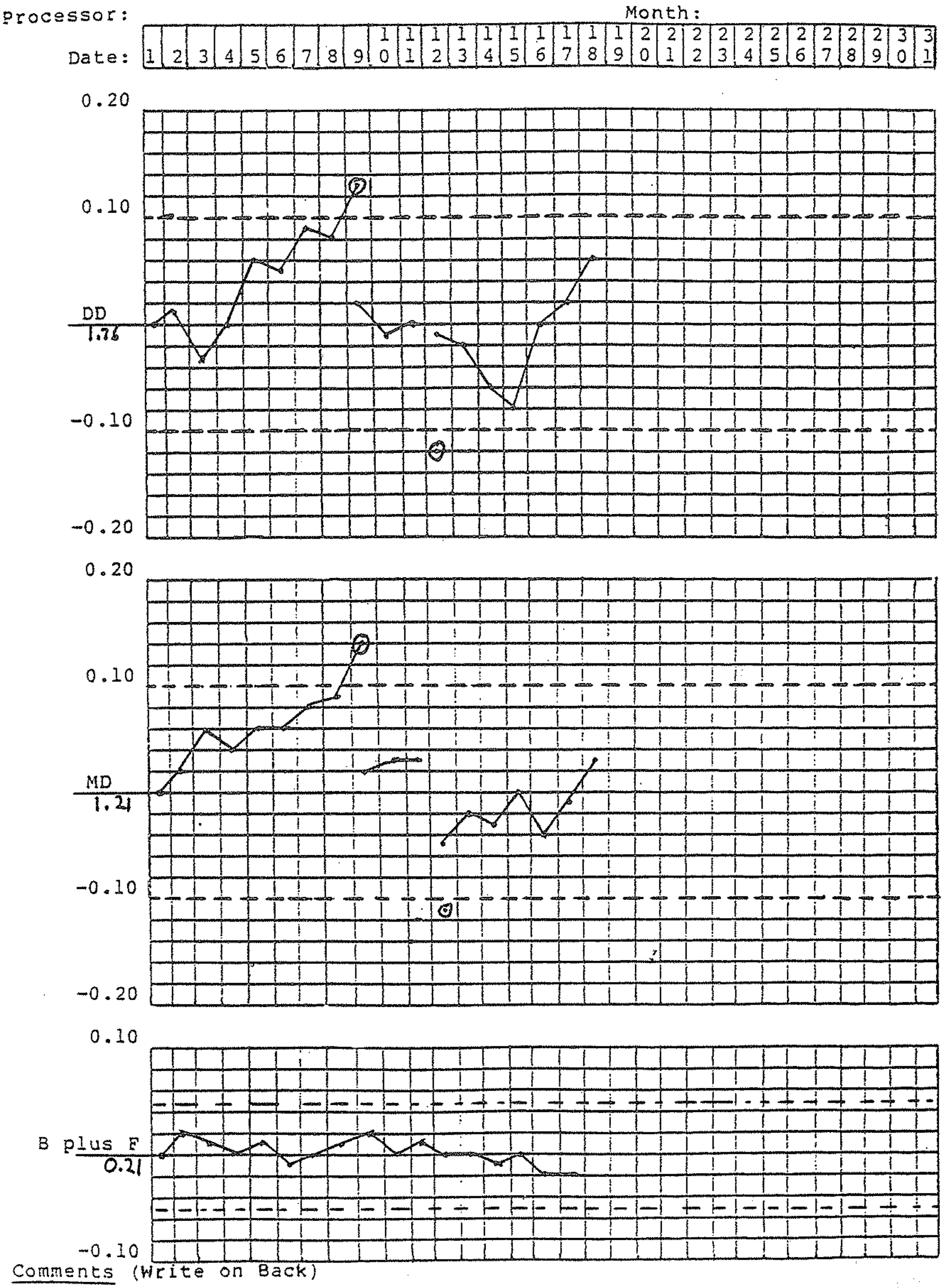

Figure 8. X-ray processing control chart examples.

10. Take the necessary action to correct the problems located in the previous step. The examples in Appendix B give some possible corrective actions for common problems. If all else fails, change the chemistry. If the developer is changed and the levels on the control strip are still outside of the control limits (after adding the recommended starter and allowing the processor to operate for 1 hour), check all possible variables again. If a second change in the developer does not bring the levels back to normal, contact the technical representative from your film and/or chemical manufacturer.

11. After the final corrections are made, additional sensitometric control strips must be processed. The new data points should be recorded on the control chart, along with the out of control points, and the specific corrective action noted on the control chart.

12. At the end of the day, follow the shutdown procedures described by the manufacturer or your processor.