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Establishing Film Processor Operating Levels and Control Limits

Equipment Required:

- Sensitometer
- Densitometer
- X-ray film
- Processor Quality Control Chart
- Establishing Film Processor Operating Levels Worksheet
- Digital thermometer accurate to at least 0.5 °F

Sensitometry Control Limits:

- Mid (or medium) Density (MD) ±0.15 Optical Density (OD)
- Density Difference (DD) ±0.15 Optical Density (OD)
- Base + Fog: within 0.05 OD of established operating levels

NOTE: MD and DD values that exceed ±0.10 should be investigated immediately before limit of ±0.15 OD is exceeded.

1. Prior to establishing processor operating levels and control limits, the processor must be cleaned and filled with fresh chemistry.
    a. Chemistry, replenishment rates, developer, fixer, and water temperatures and film transport timing mechanism must be within the film and processor manufacturers' specifications.
2. Turn on processor and allow to warm up per manufacturer's recommendations.
3. Run a sheet of clear film through the processor. This will help clean the rollers of debris.
4. Determine the temperature of the developer. Record on the Processor Quality Control chart
    a. Temperature must be within the processor and film manufacturers' specifications (usually ±0.5 °F).
5. Turn on sensitometer and follow manufacturer's instructions for warm up. Ensure glass surface of sensitometer is clean. If necessary clean with a small amount of glass cleaner and allow to dry before using. Be sure sensitometer is set to the proper light (blue or green) to match the film being used.

6. Process one sensitometric strip each day for five consecutive days. After five days you will have five sensitometric control strips.
    a. Place a sheet of film in the sensitometer and activate the sensitometer by pressing down once.
    b. Process film immediately.
    c. All films must be fed into the processor on the same side of processor tray.
7. After you have five sensitometric control strips produced over five days:
    a. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. Follow manufacturer's procedure to adjust the calibration of the densitometer if necessary. If the calibration cannot be brought into specifications by this adjustment, the densitometer must be returned to the manufacturer (or other vendor) for re-calibration.
    b. With the densitometer, read the density of each of the 21 steps for all five sensitometric control strips. If the densitometer has several aperture sizes, use the 2 mm aperture. Density reading should be taken in the center of the step. Record the data on the Establishing Film Processor Operating Levels worksheet.
    c. Using the densitometer, determine the Base + Fog for all five sensitometric control strips. Base + Fog readings can be taken over any unexposed area of the film. Record the data on the Establishing Film Processor Operating Levels worksheet.
    d. Determine the average density for each step by adding the five readings for that step and dividing by five. Record the data on the Establishing Film Processor Operating Levels worksheet.
    e. Determine the average density for the Base + Fog by adding the five readings for the Base + Fog and dividing by five. Record the data on the Establishing Film Processor Operating Levels worksheet.
8. Using the density averages in 7. above, identify:
    a. The Mid-Density (MD) step is the step where the average density is closest to but not less than 1.20.
    b. The High Density (HD) step is the step where the average density is closest to 2.20.
    c. The Low Density (LD) step is the step where the density is closest to but not less than 0.45.
    d. Determine the Density Difference (DD) by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
    e. Record on the Establishing Film Processor Operating Levels worksheet
9. On a Processor Quality Control Chart record:
    a. The facility name, processor ID, film brand name, and date (month and year).
    b. The MD average density value and the corresponding step number in the MD section of the chart.

c. The DD density value in the DD section of the chart.
d. The Base + Fog density value in the Base plus Fog section of the chart.

10. To determine the Control Limits:
    a. Add and subtract 0.15 Optical Density (OD) to the MD average density.
        i. Example: MD = 1.28; control limits = 1.43 and 1.13
    b. Add and subtract 0.15 OD to the DD value.
        i. Example: DD = 2.05; control limits = 2.20 and 1.90
    c. Add and subtract 0.03 OD to the average Base + Fog density.
        i. Example: B+F = 0.18; control limits = 0.21 and 0.15
    d. Record these density values on the Processor Quality Control Chart in the appropriate places.
11. Re-establishing operating levels and control limits (step 1 – 8 above) is necessary if there is a(n):
    a. Change in film brand or speed
    b. Change in the brand or type of chemistry
    c. Change in the film manufacturer's specifications
    d. Change in replenishment rate
    e. Change in sensitometer or densitometer (such as calibration by manufacturer or using a different set)
    f. Change in film processor
    g. Recommendation from the film manufacturer to re-establish the operating level. For example, Kodak suggests annual reestablishment.
    h. Change in the volume of film processed

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

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Establishing Film Processor Operating Levels Worksheet

- Record all 21-step densitometer readings for each sensitometric strip (each strip represents 1 of 5 consecutive days) under the appropriate step # and Base + Fog (B+F).

	Step #																				
Strip #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	B+F
1																						
2																						
3																						
4																						
5																						
Average																						

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

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

Density Difference (DD) = HD - LD ____

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Daily Processor Quality Control

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

Equipment Required:

- Sensitometer
- Densitometer
- X-ray film
- Processor Quality Control Chart
- Digital thermometer accurate to at least 0.5 °F

Sensitometry Control Limits:
Medium Density (MD) ±0.15 Optical Density (OD)
Density Difference (DD) ±0.15 Optical Density (OD)
Base + Fog within 0.05 OD of established operating levels

NOTE: MD and DD values that exceed ±0.10 should be investigated immediately before the limit of 0.15 OD is exceeded.

1. Turn on processor and allow to warm up per manufacturer's recommendations.
2. Run a sheet of clear film through the processor. This will help clean the rollers of debris.
3. Check developer temperature.
4. For automatic film processors, the temperature must be within the film manufacturer's specifications (usually ±0.5 °F). If out of manufacturer's specifications, adjust. Allow time for the temperature to stabilize before continuing. Check temperature again.
5. Turn on sensitometer and follow manufacturer's instructions for warm up. Ensure glass surface of sensitometer is clean. If necessary clean with a small amount of glass cleaner and allow drying before using. Be sure sensitometer is set to the proper light (blue or green) to match the film being used.
6. Before processing clinical images, use the sensitometer to expose and immediately process a sensitometric control strip. Place a sheet of x-ray film in the sensitometer and activate the sensitometer by pressing down once.
7. After processing, write date on film with permanent marker.

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8. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2 mm aperture.
9. Read the densities of the three steps outlined in "Establishing Processor Operating Levels and Control Limits" for MD, HD and LD, and Base + Fog. Write the densities on the film with permanent marker.
10. Determine the Density Difference (DD) by subtracting the average density of the LD step from the average density of the HD step (DD = HD-LD).
11. Plot the MD, DD, and the base + fog on Processor Quality Control Chart.
12. Determine if any of the data points exceed the control limits.
13. Circle the out-of-control data point, correct the cause of the problem and repeat the test, note the cause of the problem in the "Remarks" section of the control chart, and plot the in-control point.
14. Determine if there are any trends, (i.e. three or more data points moving in one direction [either upward or downward], in the MD, DD, or B+F). If trends are present but the data points have not, as yet, exceeded the control limits diagnostic images may be processed. However, it will be necessary to determine the cause of the trend and to monitor the processor daily to ensure that the control limits are not exceeded.
15. Actual sensitometric strips should be maintained for at least the current 6 weeks. The strips can be referenced if it is necessary to consult with a specialist on a processor problem.
16. Maintain Processor Quality Control Charts until the next completed routine inspection by Department of Public Health.

CORRECTIVE ACTIONS: Immediate action must be taken to correct any problems. Films must not be processed until processor is operating within limits set by the regulations. All corrective actions must be completed before patient films are taken, documented and records retained until they have been inspected by Radiologic Health Branch personnel.

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

Records: The Processor Quality Control Chart and records of corrective action must be kept at least until the next completed routine inspection by Department of Public Health. Sensitometric strips (film) should be maintained for at least 6 weeks.

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Troubleshooting Guide to Processor Problems

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

Indicator Deviation	Appearance on Film	Possible Causes
Increased mid-density	Increased overall density	• Wrong control film • Increased immersion time • High developer temperature • Fogged control film • Over replenishment • Unseasoned developer • Contaminated developer • Improperly mixed developer • Fixer depleted • Circulation problem • Improper safelight/storage
Decreased mid-density	Decrease overall density	• Decreased immersion time • Low developer temperature • Wrong control film • Under replenishment • Contaminated developer • Improperly mixed developer • Diluted developer
Increased density difference	Higher contrast Higher density areas darker than normal	• Decreased immersion time • Low developer temperature • Under replenishment • Unseasoned developer • Contaminated developer • Improperly mixed developer

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Decreased density difference	Lower contrast Higher densities in lighter areas and lighter densities in higher density areas	• Increased immersion time • High developer temperature • Over replenishment • Contaminated developer • Improperly mixed developer • Depleted developer • Improper safelight/storage
Increased mid-density **and** Decreased density difference	Density too high Contrast too high	• Increased immersion time • High developer temperature • Over replenishment • Contaminated developer
Decreased mid density **and** Increased density difference	Density low High contrast	• Decreased immersion time • Low developer temperature • Under replenishment
Increased Base + Fog	Overall increase in density	• Fogged film • Wrong control film • Increased immersion time • High developer temperature • Over replenishment • Contaminated developer • Unseasoned developer
Decreased Base + Fog	Overall decrease in density	• Wrong control film • Low developer temperature

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Processor Quality Control Chart

Processor: _____ Film: _____ Year: _____

Month																																						
Date																																					
Performed by																																					
Developer Temp																																					

Density Difference (DD) = Step __ - Step __

+0.15																																						
+0.10																																					
+0.05																																					
Density Difference																																					
-0.05																																					
-0.10																																					
-0.15																																					

Mid Density (MD) = Step __

+0.15																																						
+0.10																																					
+0.05																																					
Mid Density																																					
-0.05																																					
-0.10																																					
-0.15																																					

Base + Fog = Step __

+0.05																																						
Base + Fog																																					
-0.05																																					

Date	Remarks / Action Taken

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Quality Control Log

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

Test for Residual Fixer (at least every 3 months)

Date															
Performed by															
Test result (Pass/Fail)															
Appropriate person notified (Yes/No)?															

Test for Darkroom Fog (at least every 6 months)

Date								
Performed by								
Test result (Pass/Fail)								
Appropriate person notified (Yes/No)?								

Date	Remarks / Action Taken

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