

# STATE OF COLORADO

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Colorado Department  
of Public Health  
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## Procedural Guidance Hazardous Materials and Waste Management Division

Radiation Control Program, X-Ray Certification Unit

SUBJECT: Interpretation of the Quality Assurance (QA) Program and Quality Control (QC) Program for radiographic imaging systems used in the healing arts in the State of Colorado and identified in 6 CCR 1007-1, Part 6 of the *Colorado Rules and Regulations Pertaining to Radiation Control* (Regulations).

### **Basis and Purpose:**

6 CCR 1007-1, Part 6, Section 6.3.5 and 6.6.5 states that each human use facility shall have active policies and procedures in place to identify perform, and document quality assurance and quality control for all imaging systems used in the healing arts.

The Regulations categorize which types of equipment and imaging systems will require a QA and QC program. The Regulations also outline the basic and general regulatory requirements for these systems.

The Regulations reference three general pathways for quality assurance and quality control procedure(s) to be established. Those pathways include: 1) using the specifications of the manufacturer, 2) following the recommendation of a registered medical physicist (RMP) and/or 3) recommendations from a nationally recognized organization. The Regulations also include various American Association of Physicists in Medicine (AAPM) reports as references to quality assurance and quality control program.

The facility, together with a RMP, must develop a QA and QC procedure that meets the requirements of the Regulations. For those facilities that do not have a RMP on staff or through contract can develop a quality assurance and quality control program with the assistance of this guidance. Any RMP or Qualified Inspector (QI) may utilize this guidance to assist a facility in developing a QA and QC program for general diagnostic radiographic systems (not fluoroscopy, computed tomography or mammography).

A QA and QC program must be developed for each machine that falls under the Regulations of the *Rules and Regulations Pertaining to Radiation Control*, 6 CCR 1007-1, Part 6, 6.3.5 and 6.6.5. The new Regulations requires all facilities to develop and implement, for their specific imaging system, a policy and procedure to document a QA and QC program. It will be the responsibility of the RMP or QI to review with each facility their quality assurance and quality control program on an annual basis.

The purpose of the interpretive guidance is to define each section of the Regulation and provide recommendations to meet the requirement of the Rule. These recommendations are only suggested interpretations and the RMP, along with the manufacturer specifications or guidance from a nationally recognized organization, may use these guidelines to implement a quality assurance and quality control program. The overall goal of this guidance is to help guide the RMP/QI to put into place a QC/QA program that is deemed appropriate for each facility.

### **Scope:**

This guidance applies to all imaging systems and systems used for image processing, transmission of image viewing used for interpretation, except for fluoroscopic, CT or mammographic. This guidance is to be utilized by facilities, registrants, RMPs and QIs or any other individual who is responsible for setting up policies and procedures to meet 6 CCR 1007-1, Part 6, Section 6.3.5 and 6.6.5.

The RMP may choose to use this interpretive guidance to implement and develop a QA and QC program based on the needs and frequency of use of any radiographic imaging system of a facility. The RMP may choose to make recommendations to the facility for quality assurance and quality control based on their own expertise and the AAPM reports. The goal is to allow the RMP collaboration with a facility to set up an initial QA and QC program and maintain the program through annual reviews.

Dental and veterinary facilities will not be required to follow the requirements of Part 6, 6.3.5 and 6.6.5.

All Dental facilities will follow quality control Regulations stated in 6 CCR 1007-1, Part 6, 6.7.5 – 6.7.5.3.

All Veterinary facilities will follow quality control Regulations stated in 6 CCR 1007-1, Part 6, 6.8.5 – 6.8.5.2

All Mammography facilities must have quality assurance and quality control procedures that comply with 21 CFR 900 MQSA regulations.

**Supporting Regulation:**

Part 6, 6.3.5.1 “To avoid unnecessary or duplicative radiation exposure, each human use facility shall have an active image processing quality control and quality assurance (QA) program that follows manufacturers’ specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.”

**Regulation:**

Part 6, 6.3.5.2 “Each registrant that uses a hard copy imaging system with transmission viewing, whether with or without liquid chemistry, shall document that quality control and quality assurance have been performed according to specifications of the manufacturer or a registered medical physicist and/or a nationally recognized organization, including:

1. Periodic printing of a sensitometric strip or pattern;
2. Documentation of low, medium and high density calibration and that any calibration which failed to meet a manufacturer’s specification was corrected before the image printer was used to print another image; and
3. Annual review of all quality control tests.”

**Interpretation:**

This regulation refers to all laser type printers used to print images. The quality control program for all laser printers must meet the manufacturers specifications, recommendations from an RMP and/or recommendations from a nationally recognized organization for example, ACR, AAPM, or CRCPD.

Sensitometric tests should be done each day that the printer is used for image processing.

1. Documentation of the quality control should be done on forms provided in the manufacturer’s operators manual or any form developed internally or under the recommendation of a RMP. The documentation form (log) is usually found in the operator’s manual for the printer.
2. The calibrations from the sensitometric strip for the low, medium and high density indexes must be documented on a form and shall not exceed the limits set by the manufacturer, RMP or nationally recognized organization.
3. Laser printer systems that do self calibration are acceptable but documentation of the self calibration shall be kept on file for annual review.
4. All documentation shall be reviewed annually by the person in a supervisory capacity/radiation safety officer or RMP or QI.
5. A facility may be required to have in possession a densitometer for calculations if the laser printer is not self calibrating.

**Regulation:**

Part 6, 6.3.5.3 “Each registrant that uses an automatic film processor shall adopt an acceptable sensitometric quality control program.

1. Film processors used to develop radiographs shall be adjusted and maintained to meet the technical development specifications for the radiography film in use.
2. For all x-ray imaging systems, a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, shall be performed according to specifications of the manufacture and/or a registered medical physicist and/or a nationally recognized organization.”

**Interpretation:**

This regulation refers to all wet tank, automatic film processors developing radiographic images for interpretation.

1. Routine maintenance and cleaning records of the automatic film processor will be maintained according to the manufacturer guidelines.
2. All automatic film processors shall follow the manufacturer's specifications for film type, chemistry type, replenishment rates.
3. A quality control program shall follow the specifications of the manufacturer and/or a RMP and/or a nationally recognized organization with documentation of the processed sensitometric strip for speed, contrast, and base+fog. The documentation form (log) is usually found in the operator's manual for the processor.
4. The sensitometric strip should be performed each day radiographic procedures are performed prior to the development of the x-ray film. **(For example, if a facility takes radiographs daily, then a sensitometric strip should be processed daily and the speed, contrast, and base+fog shall be documented on a form. If a facility does not take radiographs daily, then the facility need only to perform the quality control sensitometric strip documenting the speed, contrast, and base+fog on a form for the days that radiographs are taken).**
5. A sensitometric strip should be performed by the service company each time the processor receives routine maintenance and cleaning.
6. Training may be necessary for individuals not familiar with processor quality control. This will be the responsibility of the facility to obtain training for individuals performing quality control. The X-Ray Certification Unit can be contacted for recommendations or the facility may contact their processor service company.
7. The quality control program shall be reviewed annually by the RMP or QI.
8. The facility may be required to have in possession, a densitometer and sensitometer to perform these calibrations.
9. The use of a step wedge may be used instead of the sensitometer. The radiographic equipment must be producing good quality radiographs consistently and a densitometer should be maintained to evaluate the step wedge in the same manner as the sensitometric strip mention in number 4. The RMP/QI should evaluate the use of a step wedge based on volume of patients, the maintenance history of the processor and chemistry use.
10. Monthly developer chemistry changes refer to only those systems that have a manual development tank system and not automatic processing units.

**Regulation:**

Part 6, 6.3.5.4 "Each registrant that uses a manual film process shall:

1. Follow applicable manufacturer's development time and temperature specifications, which shall be available for review;
2. Measure and log development temperature each day of use; and
3. Document in a written log the change of developer chemicals at least every month."

**Interpretation:**

1. For facilities that do only manual film processing, they will document the measurement of the developer temperature on a log for each day of use.
2. A written log shall be kept indicating the monthly change of developer chemistry.
3. In Part 6, 6.8.5 and 6.7.5 the monthly change in developer chemicals refers to manual tank systems only.
4. The facility will follow all manufacturer specifications for chemicals used.
5. Documentation of this log will be reviewed annually by the RMP or QI.

**Regulation:**

Part 6, 6.3.5.5 "The registrant shall control darkroom lighting such that:

1. Exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.
2. If used, daylight handling boxes preclude fogging of the film.
3. The base plus fog of an unexposed film does not exceed 0.25 optical density units when developed by the routine procedure used by the facility."

**Interpretation:**

Darkrooms will be maintained for facilities that have manual or automatic film processing. The integrity of the darkroom shall be maintained by performing a darkroom fog test.

1. The darkroom fog test shall be performed by laying an exposed film on the counter for one minute in a closed darkroom. Half of the film must be covered by an opaque medium such as a manila folder. The film is then processed through the manual or automatic film processor.
2. The optical density difference between the covered and uncovered side must be less than 0.1 optical density units. The difference must be documented. If the difference exceeds 0.1 optical density units, corrective action must be taken.
3. The base plus fog will not exceed the 0.25 optical density units as required by Regulation.
4. Documentation of this log will be reviewed annually by the RMP or QI.

**Regulation:**

Part 6, 6.3.5.7 “The registrant shall ensure that each monitor used for primary image interpretation is evaluated according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization for example, AAPM Online Report OR-03, Assessment of Display Performance For Medical Imaging Systems (April 2005), including but not limited to:

1. Frequent careful cleaning of each primary image interpretation workstation and data acquisition workstation monitor;
2. Periodic visual assessment of Society of Motion Picture and Television Engineers (SMPTE) Pattern or equivalent test pattern;
3. Initial and annual verification that monitor calibration conforms with the DICOM Part 14 Grayscale Standard Display Function (see AAPM Online Report OR-03), or equivalent:
  - a. Visualization of low contrast patches;
  - b. Visualization of spatial resolution targets;
  - c. Measurement of ambient light levels;
  - d. Measurement of the luminance from a sufficient number of driving levels;
  - e. Measurements to assure that the luminance for multiple monitors are within 5% of each other when more than one monitor is being utilized at a primary image interpretation workstation.”

**Interpretation:**

This regulation refers to all facilities using monitors that are used to interpret a digital radiograph. The rule refers to the monitor used by the physician at a review work station (RWS). These monitors at the review work station shall be maintained according to manufacturer specifications, RMP suggestions and/or guidance from a nationally recognized organization.

1. Documentation of weekly cleaning of the monitors.
2. Documentation of quality assurance and quality control may follow the recommendation of a RMP and/or manufacturer specifications.
3. For monitors without any manufacturer guidelines, the facility should set up a visual inspection to document ghosting, dead pixel evaluation, brightness and contrast.
4. For those monitors without any manufacturer guidelines, the facility can download a SMPTE pattern test to evaluate the quality assurance and quality control of the monitors.
5. Documentation of the quality assurance and quality control program for monitors will be reviewed annually by the QI or RMP.

**Regulation:**

Part 6, 6.3.5.8 “The registrant shall ensure that computed radiography cassettes and cassette readers used for primary image interpretation are evaluated periodically according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in AAPM Report 93, in a program reviewed annually by a registered medical physicist.”

**Interpretation:**

The quality control program for computed radiography cassettes and cassette readers shall be reviewed annually by an RMP. The RMP may determine how the computed cassettes and readers may be evaluated based on the manufacturer and/or the facility using computed radiography. Dental and veterinary facilities shall be **exempt** from this Rule.

**Regulation:**

Part 6, 6.6.5 “For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.”

Part 6, 6.6.5.1 “The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

1. Specifications of the manufacturer; and
2. Specifications of a Registered Medical Physicist; and/or
3. Standards of an appropriate nationally recognized organization”.

Part 6, 6.6.5.2 “Routine periodic quality control shall be comparable to the following:

1. Cassette maintenance (for example, erasure and/or screen cleaning);
2. Images inspected for evidence of clinically relevant artifacts (for example, dust and non-uniformities) with appropriate corrective action (for example, cleaning of screens) taken as needed and documented;
3. Analysis of repeated and/or rejected images;
4. Investigation of errors outside a control range;
5. Measurements using phantoms, if required (for example, in bone densitometry); and
6. Measurements of scattered radiation at the operator’s position, if required (for example, in bone densitometry).”

Part 6, 6.5.5.3 “Annual quality assurance shall be comparable to the following:

1. All quality control tests shall be reviewed annually;
2. Imaging systems shall be tested in accordance with standards and protocols published by a nationally recognized organization; and
3. The frequency of quality control testing and corrective actions taken as a result are followed and documented.”

**Interpretation:**

All other general use diagnostic imaging systems shall implement a QA and QC program by following the manufacturer specifications, or recommendations from an RMP, and/or guidance from a nationally recognized organization.

1. Film cassettes shall be maintained for cleanliness of the screen and integrity of the screen through proper periodic maintenance as determined by the RMP, qualified inspector or supervisor of a facility.
2. Screens and Cassettes used for computed radiography shall follow the guidance of Part 6, 6.3.5.8 and the RMP.
3. Artifacts on all screens whether computed radiography or film/screen shall be monitored and evaluated when the artifact could potentially affect image quality.
4. A repeat/reject analysis is required by Regulation. Suggested evaluation periods can be 3 months or 6 months depending on the volume of the facility and the recommendation of the RMP/QI. The procedure for performing the repeat/reject analysis is based on the manufacturer specifications, RMP or a nationally recognized organization. The repeat/reject analysis will be required for all imaging systems to include film, computed radiography and digital. Documentation of this quality assurance test shall be kept on file and evaluated annually by the inspector.
5. The exposure ranges for digital and computed radiography will be reviewed annually by a person designated by the radiation safety officer or RMP. The purpose of this review is to monitor radiation doses as to ensure that radiation doses are not creeping upward causing undo exposure to patients and staff.
6. Each bone densitometry unit shall maintain documentation that phantom testing is performed for each day it is used.
7. All QA and QC shall be reviewed by a RMP or QI.
8. Each facility should have a method to review their QA and QC program. The radiation safety officer shall be involved in any QA and QC program.

Authorized by: \_\_\_\_\_

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