

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

Text of regulations

California Code of Regulations, Title 17, Public Health

§ 30305.1. Quality Assurance General Provisions

§ 30308.1. Quality Assurance for Radiographic Installations (Other Than Mammography, Dental, and Veterinary Medicine)

§ 30311.1. Quality Assurance for Dental Radiography

Questions and Answers

1. Where can I learn how to perform quality assurance testing and find additional information?

Additional information can be found on the Conference Radiation Control Program Directors website at <http://www.crcpd.org/page/Publications>.

For radiographic machines:

<http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol3-Web.pdf>.

For podiatric facilities:

<http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol2-Web.pdf>.

For dental facilities:

<http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol1-Web.pdf>.

2. Our clinic uses only digital radiography/computed radiography in our X-ray department. Are there new Q.A. requirements for users who do not process film to record their radiographic images?

No. These regulations apply only to users who chemically process film to record their radiographic images.

3. We process our films manually. Do these regulations apply to us?

Yes. Section 30305.1 applies to all users who chemically process film using either manual or automatic processing. Section 30308.1 applies to users who develop clinical radiographs for diagnostic purposes with

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

automatic film processors for other than mammographic, dental, or veterinary use. Section 30311.1 applies to users who manually, or with automatic film processors, process intra-oral films for dental radiography of human beings.

4. Must a person be designated to oversee Q.A. testing?

No, but doing so will assist in achieving consistent results.

5. What type of training will be required of the person performing Q.A. and will documentation of the training be required?

The type of training is not specified; however, it is essential that the person(s) performing the Q.A. tests are familiar with the equipment, procedures, anticipated outcomes, and required documentation. The user (registrant) is required to assure that the tests are being performed correctly. Training records should be retained for inspection.

6. Does the person performing the Q.A. tests have to be a Radiologic Technologist or an X-ray Technician?

No.

7. When does this regulation take effect?

October 05, 2012.

8. Do these regulations apply to all X-ray machines users?

Section 30305.1 applies to all users. Sections 30308.1 and 30311.1 apply as specified. These regulations do not apply to X-rays used exclusively for mammography, veterinary medicine, or in non-human use applications.

9. Our facility is a veterinary clinic or veterinary hospital that uses X-ray film processors. Do these regulations apply to us?

Only requirements found in section 30305.1 apply.

10. Our dental clinic processes X-ray film. Do these regulations apply to us?

Yes; Section 30311.1 specifically applies to dental users.

11. Our clinic uses both digital and film-screen modalities. Do these regulations apply to us?

Yes; however, section 30308.1 applies only to users who develop clinical radiographs for diagnostic purposes with automatic film processors for other

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

than mammographic, dental, or veterinary use. Section 30311.1 applies to users who chemically process intra-oral films for dental radiography of human beings. Section 30305.1 applies to all users.

12. Must we stop processing X-ray films if any of the Q.A. parameters are exceeded?

Yes, until the problem is identified and corrective actions have been implemented.

13. Must we establish a Q.A. manual?

No. Your procedures must be adequate to ensure that the tests are performed correctly. Documentation of the results, problems identified, corrective actions taken, and assessment of the effectiveness of the corrective action must be available for inspection, but they need not be contained in a single manual.

14. How long must we keep Q.A. records?

Q.A. records must be maintained for at least one year from the date the test was performed.

15. What type of Q.A. records do we need to keep?

- All the Q.A. test records specified in these regulations
- Documentation of problems detected
- Documentation of corrective actions taken
- An assessment of the effectiveness of the corrective actions

16. Are electronically stored versions of the Q.A. records acceptable?

Yes; as long as the records can easily be accessed by the person responsible for doing the Q.A. test, facility staff taking X-rays, the X-ray Supervisor and Operator, and are available at the time of the inspection.

17. What does assessing the “Effectiveness of the Corrective Actions” mean?

It means determining whether the corrective actions have fixed the problem, to include repeating any test that had results falling outside the criteria specified, to determine if the action taken corrected the problem identified.

18. If we fail to conduct Q.A. tests at the required interval, must we stop processing X-ray films?

Yes, until it has been determined that the processor is operating within the

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

limits specified in section 30308.1(a)(2). Corrective actions must also be implemented to assure that the required tests are performed at the required frequencies.

- 19.** Where can we find the manufacturer's information and recommendations for handling the X-ray film we use?

It may be noted on the box. Otherwise, contact your X-ray film supplier's representative.

- 20.** Must I establish a Technique Chart that includes all the X-ray examinations that we perform?

No. The Technique Chart, for each X-ray machine, must include for each view commonly performed in the facility the information specified in section 30305.1(a)(3).

- 21.** Can we ask the person servicing our film processor to perform these Q.A. tests?

Yes. The user remains responsible to assure that the tests are performed and records maintained regardless of who is assigned to perform the tests. However, measurements must be performed each day before clinical radiographs are processed.

- 22.** Is there a specific or designated form for each of these Q.A. tests?

No. X-ray film vendors or processor service providers and professional organizations, may have established forms available for these Q.A. tests. The forms should identify baseline values and action limits.

- 23.** Can I develop my own Q.A. forms for each of the required tests?

Yes.

- 24.** Must I perform daily Q.A. tests on the days that we will not be performing or processing clinical radiographs?

No. Daily Q.A. tests are required only before clinical radiographs are processed. You are not required to perform daily tests on those days that you do not process clinical radiographs.

- 25.** What is fixer?

Also called "hypo"; this is the acidic fixing solution that fixes or hardens the radiographic image on the film. The fixer removes the unexposed and undeveloped silver bromide crystals from the film emulsion and re-hardens

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

the emulsion that has softened during the development process.

26. What is a residual fixer test?

This test evaluates how well the rinse phase of processing has removed the fixer from the film. Residual fixer chemicals left on films after processing can render radiographs useless within five years due to chemical staining.

27. How do you test for fixer retention (residual fixer)?

This can be accomplished by obtaining a fixer retention test kit that includes a residual hypo test solution and a hypo estimator test strip.

A drop of solution is placed on the emulsion side of a freshly processed film. After waiting two minutes, the area where the solution has dried is compared to the hypo estimator. Residual hypo in the film must be less than 5.0 micrograms per square centimeter.

28. What is Optical Density (O.D.)?

Optical Density, or simply density, is the degree of blackening of the film after exposure to X-rays and processing. The higher the optical density, the darker the film appears.

29. How do you measure Optical Density?

Optical density is measured with a device called a Densitometer. This equipment should be calibrated periodically against industry reference standards in accordance with its manufacturer recommendations.

30. What is Base plus Fog?

This is the level of pre-existing density of an unexposed X-ray film.

31. Where is Base plus Fog measured?

Base plus Fog is measured on any unexposed area of the film.

32. What equipment is needed to measure Base plus Fog?

Base plus Fog is measured with a device called a Densitometer. This equipment should be calibrated periodically against industry reference standards in accordance with its manufacturer standards.

33. What is a Densitometer?

A densitometer is a device used to read the optical density of an image or

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

step wedge. This equipment should be calibrated periodically against industry reference standards in accordance with its manufacturer standards.

34. What is a Sensitometer?

A sensitometer is a device that produces highly reproducible step wedge image in an X-ray film, and is used to monitor the performance of the developer in a film processor.

35. What factors affect Base plus Fog?

- Film storage condition
- Darkroom light
- Developer temperature
- Developer integrity ("spent" or contaminated developed)

36. What is Mid-Density?

Mid-Density, or Speed Index, can be defined as the step closest to 1.00 plus Base plus Fog or 1.20 O.D

37. What factors affect Mid-Density?

- Developer temperature
- Fog level of the film
- Developing time
- Developer replenishment rate

38. What is Density Difference?

Density Difference, or Contrast Difference or Contrast Index, is the difference between the step that produces a light shade of gray (0.25 O.D. plus Base plus Fog) and the step that produces upper range of viewable light on an unexposed film (2.00 plus Base plus Fog).

Typically, the density difference is the measured optical density of the Step closest to 2.20 minus the measured optical density of the step closest to 0.45.

39. What factors affect the Density Difference?

- Fog level on film
- Developer temperature
- Development time
- Developer integrity

40. What is Darkroom Fog?

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

Darkroom fog is darkening of the film that does not come from being exposed to an X-ray source.

41. What factors contribute to fog on an X-ray film?

- Improper film storage, such as excessive heat or humidity
- Accidental exposure to white/bright light
- Improper processing
- Using film past the documented expiration date
- Light leaks in the darkroom

42. Our facility does not currently own a sensitometer or a densitometer. Will we be required to purchase a sensitometer and a densitometer?

No. You are not required to own the equipment necessary for performance of the Q.A tests. You must ensure that the tests are performed accurately and have access to the necessary equipment at the required test intervals.

43. What is Contrast in an X-ray film?

Contrast is the difference in O.D. between areas of interest in an X-ray film. Subject contrast is the differential attenuation of the X-ray beam by the subject being radiographed. Film contrast is a characteristic of the film.

44. What factors affect Contrast in an X-ray image?

- Subject contrast
- Film contrast
- Processing
- Base plus Fog

45. If we use both digital processing and chemical film processing for dental radiography, do these regulations apply to us?

Yes, but only for the intra-oral film radiography use. These regulations apply to users who chemically process film, either manually or with an automatic processor, to record their radiographic images.

46. What should the dental reference film look like and how long are we required to keep the daily Q.A. film?

The reference film should be a standard exposed dental film image meeting the interpreting dentists' criteria for image density, contrast, sharpness and overall quality to which subsequent dental X-ray films are compared to assess image quality consistency.

Medical and Dental Quality Assurance (Q.A.) Regulations Frequently Asked Questions

47. How will dental image density, contrast, sharpness and overall quality be measured?

These will be measured by a visual check; the density may also be measured with a densitometer.

48. What type of documentation will be required to demonstrate compliance?

The inspector will review documentation showing that the required tests were performed and at the right frequency, problems were identified, corrective actions were implemented, and assessment of the effectiveness of corrective action was made to evaluate compliance.

49. Section 30308.1(a)(1) requires that each processor used to develop clinical radiographs be adjusted and maintained to meet the manufacturer's processing specifications for the highest speed radiographic film used clinically. We process our mammography films in only one processor. Must all of our processors meet the processing specifications for mammography film even though they are not used for processing mammography film?

Each processor must be adjusted and maintained to meet the manufacturer's processing specifications for the highest speed radiographic film used clinically that is processed in that processor.