Section 5

Legal Issues, Quality Assurance, and Infection Prevention
1. Pronounce, define, and spell the Key Terms.

2. Discuss the three major categories of legal considerations, including:
   - Describe the types of laws that affect the practice of dental radiography.
   - Describe the Consumer-Patient Radiation Health and Safety Act.
   - Describe the components of informed consent with regard to dental imaging.
   - Identify the individual who legally “owns” the dental images.
Introduction

- As a dental assistant, it is your responsibility to understand the laws that apply to you when you are exposing dental radiographs.

- Both federal and state regulations control the use of dental x-ray equipment.

- To ensure the highest quality dental images and the least risk for exposure to patients and personnel, a quality assurance program is necessary.

- Regardless of the imaging technique used, the potential is always present for cross-contamination of equipment and environmental surfaces if good infection control procedures are not practiced.
There are three major categories of legal considerations regarding the use of images in dentistry:

- Federal and state regulations regarding x-ray equipment and its use
- Licensure for individuals exposing dental images
- Risk management for avoiding potential lawsuits
Federal and State Regulations

- The use of dental x-ray equipment is regulated by both federal and state regulations

- All dental x-ray machines manufactured or sold in the United States after 1974 must meet federal regulations
  - These include safety specifications for minimum filtration and accuracy of the milliamperage time and kilovoltage setting

- All x-ray equipment is also subject to state, county, or city radiation health codes
Licensure Requirements

- The Consumer-Patient Radiation Health and Safety Act is a federal law that requires persons who take dental radiographs to be properly trained and certified.
  - It is up to the individual state to determine its own policy regarding the qualifications of individuals exposing radiographs.

- X-ray certification requirements for the dental assistant vary from state to state.
  - Some states require certification by the Dental Assisting National Board; other states may require an additional examination.
  - Each state deals with dental radiography differently.
Risk Management

- Risk management policies are designed to reduce the likelihood of a malpractice lawsuit against the dentist.

- The dental assistant has an important role in risk management:
  - The dental assistant must be careful never to say anything negative about the x-ray equipment, or how it is working.
  - Statements made without thinking (such as “The timer must be off,” “This thing never works right,” or “The solutions are weak”) are unnecessary and can make the patient feel uncomfortable.

- Statements made by anyone at the time of an alleged negligent act are admissible as evidence in court.
Informed Consent

- It is the dentist’s responsibility to discuss the need for radiographs and treatment procedures with the patient.
- The dental assistant may participate in the process of obtaining informed consent.
- Patients must give informed consent for dental radiographs, as well as for other procedures.
For Valid Informed Consent

- The patient must be provided with the following information in lay terms:
  - The risks and benefits of imaging procedures
  - The person who will be exposing the images
  - The number and type of images
  - The consequences of not having the images
  - Any alternative diagnostic aids that may provide the same information as dental images
Under state laws, the supervising dentist is legally responsible, or liable, for the actions of the dental auxiliary. This is called *respondeat superior* doctrine. It means that the employer is responsible for the actions of the employee.

Even though dental assistants work under the supervision of a licensed dentist, they can also be held legally liable for their own actions.
Whether it is conventional film or digital images, they are part of the patient’s dental record and are regarded as a legal document.

It is very important to document the exposure of dental radiographs:
- The number of films exposed, as well as the quality of the radiographs, may be an important issue in a malpractice suit.
- Radiographs that are of poor quality and are nondiagnostic reflect poorly on the dentist.
The dental record must include the following information:

- Informed consent
- The number and type of radiographs exposed
- The rationale for exposing the radiographs
- The diagnostic interpretation
Dental images are the property of the dentist, even though the patient, or the patient’s insurance company, paid for them. This is because dental radiographs are a part of the patient’s records.

Patients may request a copy of their images; this request should be written and signed by the patients. Make an entry in the chart stating when and to whom duplicate or digital dental images were sent. Never give or send original radiographs to a patient.
Dental images and other dental records should be retained indefinitely
- Statutes of limitations may vary

The question of when to destroy or discard a patient record may not always have a simple answer
- Patient records and computer data must be stored carefully so they do not become damaged or lost

Computer files should always be backed up both within the dental office and at an off-site storage facility
Digital Files Security

- An advantage of digital files is that they can be sent over computer networks.
- You must check with local, state, and federal regulations about patient confidentiality.
- It may be necessary to encrypt the files or use virtual private networks (VPNs) rather than sending files over the public Internet.
Patient Refusal of Dental Imaging

- When this occurs, the dentist must decide whether an accurate diagnosis can be made without images and whether treatment can be provided.
  - In most cases, a lack of images compromises the patient’s diagnosis and treatment.
  - The use of dental radiographs is now the accepted standard of care.
Every effort should be made to educate the patient about the importance of dental imaging.

- No document can be signed that totally releases the dentist from liability for treating a patient without taking dental images.
- Even if the patient suggests signing a release or waiver that would release the dentist from liability, it would be considered invalid if an injury were to result.

It should be recorded in the patient’s record if a patient refuses recommended images.

- The dentist must then choose whether or not to continue treating this patient.
As a dental assistant, you should understand and be sensitive to the patient’s concern and fears about exposure to radiation during dental imaging.

- The dental assistant is often the person to whom the patient feels most comfortable confiding these fears.

- The dental assistant can explain to the patient just how important dental imaging is in detecting diseases and planning treatment.

- Patients can be informed of the federal and state laws enacted for their protection.

- Educational materials are available.
3. Discuss quality assurance in the dental office, including:
   • Name the annual tests recommended for x-ray equipment.
   • Describe quality control tests for processing solutions, including the use of a reference radiograph and stepwedge radiograph.
   • Describe the components of a quality assurance program.
Quality assurance (QA) is a way of ensuring that everything possible is being done to produce high-quality diagnostic images.

It includes both *quality control tests* that monitor dental x-ray equipment, supplies, and image processing.

It also involves *quality administration procedures*, including keeping schedules of maintenance and record-keeping logs.
Quality Control Tests

- Specific tests that are used to monitor dental x-ray equipment, supplies, and film processing

- Tests designed to identify minor malfunctions include:
  - Variations in radiation output
  - Inadequate collimation
  - Tubehead drifting
  - Errors in timing
  - Inaccurate kilovoltage and milliamperage readings
Quality Control Tests (Cont.)

- When not in use, always leave the tubehead and extension arm in a closed position
- The weight of the tubehead on an open extension arm can weaken the unit and cause the tubehead to drift during exposure
Types of Quality Control Tests

Dental film: Test each new box for freshness.
Dental x-ray machine: Calibrate equipment regularly.
Cassettes and phosphor storage plates (PSPs): Clean and examine for scratches.
Safelighting: Check for light-tightness in darkroom.
Automatic processor: Follow manufacturer’s recommendations carefully regarding maintenance.
Manual processor: Replenish daily and change every 3 to 4 weeks.
Dental X-Ray Machines

- Regulations require that dental x-ray machines be inspected periodically.
  - Some state and local regulatory agencies provide inspections of dental x-ray equipment without charge as part of their registration and licensing procedures.

- Dental x-ray machines also must be *calibrated*, or adjusted for accuracy, at regular intervals.
  - These tests are easy to perform and require only basic test materials and test logs to record the results.
X-Ray Machine Quality Control Steps

1. Test output of x-rays.
2. Test size of focal spot.
3. Test tubehead for stability.
4. Test timer for accuracy.
5. Test milliamperage.
6. Test kilovoltage.
Dental X-Ray Film

- Check each box of film while opening it

- Follow these steps to test film for freshness:
  - In the darkroom, unwrap one unexposed film from the newly opened box
  - Process the film with the use of fresh chemicals
  - Check the results
  - If the processed film appears clean with a slight blue tint, the film is fresh and has been properly stored and handled and is safe to use
  - If the processed film appears fogged, the film has been improperly stored or exposed to radiation and must not be used
Phosphor Storage Plates

- Reusable *phosphor storage plates* (PSP) require less radiation exposure than film
Intensifying screens inside the extraoral cassette should be periodically checked for dirt and scratches.

- Screens should be checked monthly with a commercially available cleaner.
- After cleaning, an antistatic solution should be applied to the screen to prevent static electricity.

- Screens that appear visibly scratched should be replaced.

- Cassettes should be checked for worn closures, light leaks, and warping, which may result in fogged and blurred images; damaged cassettes must be repaired or replaced.
Steps to test the cassette for adequate film-screen contact:

- In the darkroom, insert one film between the screens in the cassette
- Place a wire mesh test object on top of the loaded cassette
- Using a 40-inch target-film distance, direct the central ray perpendicular to the cassette
- Expose the film with the use of 10 mA, 70 kVp, and 15 impulses
- Process the exposed image
Steps to test the cassette for adequate film-screen contact:

- View the film on a *view box* in a dimly lit room at a distance of 6 feet.
- Check the results.
- If the wire mesh image seen on the film exhibits uniform density, good image receptor-screen contact has taken place (the cassette and screen are safe to use).
- If the wire mesh image that can be seen on the film exhibits varying densities, poor receptor-screen contact has taken place.
- If the film-screen contact is poor, the cassette should be repaired or replaced.
A properly functioning view box is necessary for the interpretation of conventional radiographs.

The view box contains fluorescent bulbs that emit light through an opaque plastic or Plexiglas front.

The view box should emit a uniform and subdued light when functioning properly.
The view box should be periodically checked for dirt and discoloration of the Plexiglas surface
- The surface of the view box should be wiped clean daily
- Permanently discolored Plexiglas or blackened fluorescent bulbs must be replaced
View Box with Clean Plexiglas and New Bulb
Darkroom Lighting

- Check the darkroom for light leaks every 6 months:
  - While standing in the darkroom, turn off all the lights, including the safelight
  - Once your eyes become accustomed to the darkness, look around the room for any signs of white light
  - Check the results
  - If the darkroom has no visible light leaks, the room is safe for processing films
  - If light leaks are present, they must be corrected with weather stripping or black electrical tape before film processing is continued
Use the coin test to check the safelight:

- Turn off all the lights in the darkroom, including the safelight
- Unwrap one exposed film and place it on a flat surface at least 4 feet away from the safelight, with a coin on top of film
- Turn on safelight and allow film and coin to be exposed to safelight for 3 to 4 minutes
- Remove coin and process the film as usual
- Check the results
- If no image is visible on film, the safelight is functioning and it is safe to process other films
- If image of the coin and a fogged background appear on the processed film, safelight is not safe to use with that type of film
Safelight Test Example
Film Processing

- Perform quality control procedures routinely
  - Film processing is one of the most critical aspects of a quality control program
  - It must be monitored on a daily basis

- Manual processing

- Automatic processing
Manual Processing

- The thermometer and the timer must be checked for accuracy
  - The temperature and levels of the water bath, developer, and fixer solutions also must be checked
  - Strictly follow the processing time and temperature recommendations of the solution manufacturer
Check the water circulation system, the solution levels, the replenishment system, and temperatures

Always follow the manufacturer’s procedure and maintenance directions carefully

Each day, you should process two test films in the automatic processor
Follow these steps to verify the functioning of the automatic processor:

- Unwrap two unexposed films; expose one to light
- Process both films in the automatic processor
- Check the results
- If the unexposed film appears clear and dry, and if the film exposed to light appears black and dry, the automatic processor is functioning properly
- If the unexposed film does not appear clear and dry, or if the exposed film does not appear completely black and dry, the automatic processor must be checked
The most critical component in the quality control of film processing
- You must replenish the processing solutions daily and change them every 3 to 4 weeks, as recommended by the manufacturer

As an alternative to using the calendar to determine the freshness of solutions, quality control tests can be used to monitor the strength of the developer and fixer solutions
- You should check the processing solutions each day before any patient films are processed
Developer Strength

- As the developer loses strength, the time-temperature chart is no longer accurate
- An easy way to check the strength of the developer solution is to compare film densities against a standard
- This can be done with a reference radiograph or a stepwedge radiograph
To create a reference radiograph:
- Expose fresh film, using correct exposure factors
- Process the film using fresh chemicals at the recommended time and temperature
- View the reference radiograph and the daily radiographs side by side on a view box
- Check the results
If the densities seen on the reference radiograph match the densities seen on the daily radiographs, the developer solution strength is adequate.

If the densities seen on the daily radiograph appear darker than those seen on the reference radiograph, the developer solution is either too too concentrated or too warm.

Weakened or concentrated developer solution must be replaced.

If the developer solution is too warm or too cold, the temperature must be adjusted before patient films are processed.
A stepwedge is a device that is constructed of layered aluminum steps.

- When a stepwedge is placed on top of a film and then is exposed to x-rays, the different steps absorb varying amounts of radiation.
- When the film is processed, different densities are seen on the dental radiograph.
Steps to Create Stepwedge Radiographs

- Use a total of 20 fresh films
- Place an aluminum stepwedge on top of one film
- Expose the film
- Then expose the remaining films using the same exposure factors
- Using fresh chemicals, process only one of the exposed films
  - This processed radiograph will exhibit different densities as a result of the stepwedge, and it becomes the standard stepwedge radiograph
Steps to Create Stepwedge Radiographs (Cont.)

- Store the remaining 19 exposed films in a cool, dry area protected from x-radiation
- Each day, after the chemicals have been replenished, process one of the exposed stepwedge films
- Compare the standard stepwedge radiograph and the daily radiograph side by side on a viewbox
- Compare the densities seen on the daily radiograph with the densities seen on the standard radiograph
Steps to Create Stepwedge Radiographs (Cont.)

- Check the results
- Use the middle density seen on the standard stepwedge radiograph for comparison
- If the density on the daily radiograph differs from that on the standard stepwedge radiograph by more than two steps, the developer solution is depleted and must be changed before patient films are processed
Radiograph of a Stepwedge
Fixer Strength

- When the fixer solution loses its strength, the film takes a longer time to “clear” or become transparent, in unexposed areas.
- When the fixer is at full strength, a film should clear within 2 minutes.
Follow these steps to monitor the strength of the fixer:

- Unwrap one unexposed film and immediately place it in the fixer solution.
- Check the film for clearing. Note the amount of time the film takes to clear.
- If the film clears in 2 minutes, the fixer strength is adequate.
- If the film is not completely clear in 3 to 4 minutes, the fixer is depleted.
- The fixer solution must be replaced before patient films are processed.
Quality Administration Procedure

- Quality administration deals with the management of the QA program in the dental office
  - Description: Detailed, written description of the QA plan available for all staff members
  - Monitoring: A written monitoring schedule should be posted in the office
  - Maintenance: Record-keeping log of all quality control tests with specific details
  - Evaluation: Written plan for periodic evaluation and revision of existing QA program
  - Training: In-service training for all staff members to upgrade and improve imaging techniques and processing procedures
Discuss infection control, including:

- Implement the Centers for Disease Control and Prevention (CDC) guidelines for infection control in dental radiology.
- Explain the infection control requirements for preparing a radiography operatory.
- Describe the infection control protocol when making exposures using conventional dental x-ray film.
- Describe the infection control protocol when making exposures using phosphate storage plates.
- Describe the infection control protocol when making exposures using digital sensors.
- Describe procedures during and after x-ray exposure.
- Describe procedures during x-ray film processing.
Dental radiography presents unique infection control problems because of the potential for cross-contamination of equipment and environmental surfaces with blood and saliva.

The operator places the image receptor (film, PSP, or sensor) into the mouth, moves to the exposure controls outside the operatory, and then returns to remove the image receptor or reposition it in the mouth.
There is also cross-contamination in the darkroom, or when scanning PSPs, and with use of the computer and mouse.

- Direct digital imaging can reduce the potential for cross-contamination of surfaces caused by contaminated film packets or PSP wrappers and holders.
- Digital sensors and PSPs, however, require careful placement and removal of barriers to avoid contamination.
The CDC has recognized dental radiology as a potential source of cross-contamination and has provided recommendations for dental radiology in the *Guidelines for Infection Control in Dental Health-Care Settings – 2003*
The first step in the preparation of the operatory is to identify the surfaces to be protected with barriers or disinfected with a high-level surface disinfectant.

In general, surfaces that cannot be easily cleaned and disinfected should be protected with barriers, usually plastic or foil.

Surface barriers are preferred on electrical switches because of the possibility that the cleaner and disinfectant may cause an electrical short.
The tubehead, position indicator device (PID), control panel, and exposure button must all be covered or carefully disinfected.

The lead apron should be considered contaminated and wiped down with a disinfectant after each use.
The back and arms of the chair, the headrest, and the headrest adjustment controls must all be covered or disinfected.

Once the radiography operatory is set up, you can set up the image receptors and holders.
Work Area

- The work area where the films, PSPs, or sensors and positioners are placed during exposure should be disinfected
  - Then a barrier, such as a paper sheet, paper towels, or plastic cover, should be placed

- Once the procedure is completed, discard the barriers
  - If counter surfaces are not protected by barriers, or if the barriers have become torn or damaged, they should be cleaned and disinfected
Maintaining the Work Area
Equipment and Supplies

- Before beginning the procedure, gather all necessary supplies to decrease the chance of cross-contamination.
  - For example, think about the type of film or sensor positioning devices, barrier sleeves, cotton rolls, and bitewing tabs, etc. that you may need.

- If you need additional supplies during the procedure, use overgloves (food handler’s gloves), or ask for assistance.
Film and Phosphor Storage Plates

- Dispense the film or PSPs from a central area in a disposable container, such as a paper cup.
  - Film
  - PSPs
  - Digital Sensors
  - Film and Sensor Positioning Instruments
Once films are removed from the mouth, they are obviously contaminated and should be handled only with gloved hands.

One technique that is used to minimize contamination is to place a clear-plastic barrier envelope over the film packet.

Some commercially available films are enclosed in a clear-plastic barrier packet.

Barrier-protected film packets are exposed and brought to the processing area. The barriers are contaminated and one must remove them carefully without touching the inner packet, so the packet can be handled with bare hands.
PSPs

- PSPs are reusable and must be placed in a sealed barrier packet before exposure.
- Caution must be used to prevent cross-contamination when removing the plate from the barrier packet.
Protective Barrier on X-Ray Film
Digital Sensors and Positioning Instruments

- Sensors cannot withstand heat sterilization or immersion in a high-level disinfectant
  - CDC recommends at a minimum using an FDA-cleared plastic barrier
  - A barrier is placed over the sensor and part of the attached cable (unless a wireless sensor is used)

- Image receptor positioning instruments that are placed in the patient’s mouth are semi-critical items that should be sterilized before reuse
  - The alternative is to use disposable positioners and discard them after a single use
Procedures During and After X-ray Exposure

- Operator preparation
- Drying of exposed film or PSP
- Collection of Contaminated Films/PSPs
- Positioning Instruments
- Disposal of Contaminated Items
- Hand washing
- Surface Disinfection
Always wear gloves and protective clothing while exposing images and handling contaminated items

- You should also wear a mask and eyewear if there is a likelihood that blood or other body fluids may spatter
- Masks also are indicated if you or the patient has a cough or a cold

- After putting on gloves, be careful not to touch any surfaces that are not covered
Placing the Lead Apron
Drying of Exposed Film or PSP

- The contaminated film or PSP packet is the major source of cross-contamination during imaging procedures
  - When you remove the film packet or PSP from the patient’s mouth, it is coated with saliva (or occasionally, contaminated with blood)
  - For this reason, you must always wear gloves while handling contaminated film packets or PSPs
Drying of Exposed Film or PSP (Cont.)

- After you remove each exposed receptor from the patient’s mouth, wipe saliva off using a dry 2 x 2-inch gauze sponge or a paper towel
- Do not attempt to sterilize the film or the PSP packet or sensor
Drying of Exposed Film or PSP (Cont.)

- Some dental film manufacturers permit light spraying of the contaminated film packet with disinfectant spray.
- Immersion of the packet in a disinfecting solution can result in the solution’s seeping into the emulsion and damaging the image.
- It is always the best policy to check with the manufacturer regarding infection control protocol.
Collection of Contaminated Films/PSPs

- Once dried, each film must be placed in a disposable container paper cup that is labeled with the patient’s name.

- While gloved, remove the sealed barrier, and place the PSP into a black transfer box.
  - These containers will be used to transport films to the darkroom and PSPs to the scanner.
  - If PSPs will be scanned immediately, there is no need to store them in the transfer box.

- Be careful not to touch the outside surface of paper cup or transfer box with gloved hands.

- To prevent film fog caused by radiation, never place the container in a room where additional films are being exposed.

- Exposed films or PSPs should never be placed in the operator’s laboratory or uniform pocket.
Positioning Instruments

- During exposure, always take the positioning instruments from the covered work area to the patient’s mouth and then back to the covered area.
- Never place contaminated film holders on an uncovered surface.
Disposal of Contaminated Items

- When you finish all the exposures, all contaminated items must be discarded, and any uncovered surfaces must be disinfected.
- You must wear gloves while disposing contaminated items, including disposable surface coverings, packets, barriers, etc.
- All covered surfaces must be uncovered carefully; be sure not to touch actual surfaces with gloved hands.
After all contaminated items have been removed and disposed, remove your gloves and wash your hands.
Surface Disinfection

- While wearing protective eyewear and chemical-resistant utility gloves, clean and disinfect any uncovered areas in the radiography operatory that were contaminated during exposure
  - Use hospital-grade disinfectant that is registered and approved by the Environmental Protection Agency
Transporting Film

- You should never touch the disposable container with your gloved hands
- Only after the gloves have been removed, your hands washed and dried, the patient dismissed, and the area cleaned and disinfected, should you carry the container with contaminated films to the darkroom