I. **Description**

To describe the procedures for the safe use of diagnostic x-ray equipment at UNC Health Care.

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II. **Rationale**

NC Regulations for the Protection Against Radiation issued by the NC Radiation Protection Section (RPS) require UNC Health Care to implement a radiation protection program for the safe use of diagnostic x-ray equipment. This policy applies to all x-ray equipment, including fluoroscopy units, CT scanners, and accelerator on-board imagers.

III. **Policy**

A. **ALARA Policy**

1. In addition to meeting the occupational and public dose limits as specified in section 0.1600 of the North Carolina Regulations for Protection Against Radiation, efforts shall be made to maintain personnel, public, and patient radiation exposure due the use of diagnostic x-ray equipment at UNC Health Care at ALARA (“As Low As Reasonably Achievable”) levels.

2. In general, these efforts are documented in the form of a radiation protection program and quality control program. Basic components of these programs include:
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- A personnel monitoring program
- A image processing QC program
- An x-ray equipment survey/preventive maintenance program
- A continuing education and in-service training program

B. Operator Qualifications

1. All x-ray equipment (other than dental x-ray equipment) shall be used under the direction or supervision of a qualified physician.

2. The operation of x-ray equipment is defined as depressing the control switch and activating the production of x-rays used for imaging procedures.

3. Only qualified physicians, engineering and physics staff members, and those technologists and radiation therapists who are ARRT-registered, have graduated from an accredited educational program, or are in-training for ARRT registration shall be authorized to operate x-ray equipment. Technologists and therapists must obtain their certification within one year of their employment begin date.

4. Dental x-ray equipment shall only be used under the direction or supervision of a qualified physician or dentist.

5. Only qualified physicians, dentists, dental hygienists, dental assistants, engineering and physics staff members, and radiologic technologists shall be authorized to operate dental x-ray equipment.

6. Exceptions to the above requirements must be approved by the Radiation Safety Subcommittee (RSS).

C. Indications for the Use of Diagnostic X-Rays

1. Examinations for diagnostic x-ray procedures shall be ordered by a Licensed Independent Practitioner (Physician, Dentist, Physician Assistant and Nurse Practitioner).

2. Examination should be requested specifically to produce information relating to the patient's clinical condition.

3. The request should reflect the provider's knowledge of the clinical condition. The examination should not be repeated merely for convenience.

4. Because suboptimal image quality (due perhaps to positioning or patient motion) may compromise patient care, retakes may be performed upon the discretion of the qualified x-ray equipment operator or if requested by a Licensed Independent Practitioner.

5. It should be kept in mind that not exposing the patient gives the largest dose reduction.

6. The Clinical Staff of the Radiology Department is available for consultation on diagnostic examinations.

D. Exposure Control and Beam Limitation

1. The exposure to the patient shall be kept to the practical minimum consistent with clinical objectives.

2. Target exposure indicator values are to be established for all digital imaging systems.
a. Technologists are to monitor the exposure indicator values to ensure they are within the target range.

b. This helps ensure that an appropriate amount of radiation is delivered to the detector.

3. The smallest practical field sizes and shortest exposure times shall be employed. Exception: Long exposure times may be required for breathing technique studies.

4. The possibility of reducing dose by techniques utilizing high tube potential and low current shall be considered, as long as image quality is not compromised.

5. Particular care shall be taken to limit the useful beam to the smallest area consistent with clinical requirements and to align accurately the x-ray beam with the patient and image receptor.

6. If available, the AEC (Automatic Exposure Control) feature should be utilized (with the photocell in the appropriate location) for all exposures.

7. If AEC is not available (as with mobile radiographic or dental equipment) or if one is not functioning properly, manual techniques must be utilized.

8. Manual technique charts:
   a. Technique charts indicating the exposure factors which normally yield an optimal image for a body part of specific size and position shall be available for each x-ray tube capable of making radiographic exposures and shall be used whenever applicable.
   b. Technique charts shall also provide the following information:
      (1) type and size of image receptor system to be used
      (2) type and ratio of grid (when applicable)
      (3) source-to-image distance (SID)
      (4) type and placement of gonad shielding to be used
   c. Anatomical programming, when used in conjunction with a routine filming protocol, may meet technique chart requirements.
   d. Administrative controls are an acceptable means of rendering a fluoroscope “incapable” of use in “radiographic mode.”

9. Gonadal shielding of not less than 0.5 mm of lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct or useful beam, except for cases in which the clinical objectives of the examination would be compromised.

10. Gonadal shielding is not recommended as routine practice during CT scanning (dose to the gonads is primarily from internal scattering). Shielding should however be provided upon request by the patient, which will serve the emotional well-being of the patient more than materially altering radiation dose.

11. Gonadal shielding shall never be used as a substitute for careful patient positioning, proper collimation of the beam, and appropriate exposure techniques.

E. Holding Patients During Diagnostic X-Ray Procedures

1. Mechanical supporting or restraining devices shall be used when a patient or image receptor must be held in position for the procedure.

2. If a patient must be held by an individual, that individual shall be protected with appropriate shielding devices of at least 0.25 mm lead equivalence for whole body protection and at
least 0.5 mm lead equivalence for any part of the holder’s body that is exposed to the primary x-ray beam.

3. Preferably, the individual holding the patient should be a member of the patient's family or non-radiation worker.

4. Minors or pregnant females may not be used for holding.

5. The operator shall provide radiation safety instructions to the holder to maintain doses ALARA.

6. No individual shall be used routinely to hold patients or image receptors.

7. In general, imaging professionals should not hold patients during x-ray exams. However, it may be necessary under exceptional circumstances when there is no alternative.

F. Protection of Professional Staff and Ancillary Personnel

1. Only persons whose presence is necessary shall be in the room during x-ray exposures.

2. All individuals shall be positioned such that no part of the body not protected by at least 0.5 mm lead equivalence lead apron or whole body protective barrier will be exposed to the useful beam.

3. All persons who are subject to direct scatter radiation shall be protected by lead aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.

4. The shielding integrity of protective apparel must be evaluated at least one time per calendar year.

5. The operator shall remain behind the protective barrier provided for their protection during exposures at permanent installations.

6. Operators must be able to observe the visible exposure indicator and hear the audible signal at or from the protective barrier provided.

7. Exposures are to be made with doors to the x-ray room closed with the following exceptions:
   a. Corridor doors of the Dental Clinic.
   b. Doors leading to the Tech Work Area of Main Radiology.
   c. Exposures should be avoided when individuals are in or near these doorways.

8. Facilities performing x-ray procedures shall be designed such that no individual member of the public or a person who is occupationally exposed will receive an annual radiation dose in excess of the annual dose limits as specified in the North Carolina Regulations for Protection Against Radiation.

G. Bone Densitometry X-Ray Equipment Procedures

1. A restricted area of 6 feet is to be maintained around bone densitometry equipment, e.g., DEXA and QCT, and kept clear of unnecessary persons during exposures.

2. Persons who are subject to direct scatter radiation shall be protected by lead aprons or barriers when holding a patient or otherwise directly adjacent to the patient.

3. Operator positions should be at least 6 feet from the patient during exposures, or as far away as practical due to room space limitations.

4. Unless positioned further from the patient, operators should remain in the approved operator position during exposures.
H. Additional Procedures for Mobile X-Ray Equipment

1. Mobile equipment shall be used only for examinations where it is impractical to transfer patients to permanent installations.

2. Each operator of mobile equipment, prior to making an exposure, shall ask individuals whose presence is not required to leave the room until the exposure is complete.
   a. It may not be possible for all individuals to leave the room in areas such as the PACU or ED, however the operator is responsible for making sure individuals are located as far away as practical and protected in accordance with the ALARA policy.

3. Individuals subject to direct scatter radiation, including operators of mobile equipment, shall be protected by lead aprons or whole body protective barriers of not less than 0.25 mm lead equivalent, with the following exceptions:
   a. Mobile radiography of infants in the newborn nursery and ICU areas.
   b. Other patients who are greater than 6 feet from the patient being imaged.

4. The operator shall also:
   a. Stand as far as possible (at least 6 feet) from the x-ray tube head and the nearest edge of the image receptor.
   b. Give an audible warning before exposure is made.

I. Special Considerations for the Use of Fluoroscopic Equipment

1. Medical fluoroscopy shall be performed only by or under the immediate supervision of a physician or physician extender properly trained in fluoroscopic procedures.
   a. All providers who operate or supervise the operation of x-ray producing equipment must show documentation that they meet one of the following requirements for radiation safety training:
      (1) Board certified, or Board eligible in Diagnostic Radiology, Interventional Radiology, Interventional Cardiology, Radiation Oncology, or
      (2) Board certified in a specialty, which includes formal competency-based training consisting of didactic and supervised hands-on experience relating to the operation of radiation-producing equipment, or
      (3) Successful completion of the UNC Hospitals fluoroscopy radiation safety training program described below and approved by the Radiation Safety Subcommittee.
   b. The UNC Hospitals fluoroscopy radiation safety training program consists of the following components:
      (1) An on-line training module for the safe use of fluoroscopic equipment with successful completion of the post-test (80% correct) to document that the candidate has passed an examination testing his/her knowledge of fluoroscopic radiation management. This training must be completed prior to initial use of fluoroscopic equipment and every two years thereafter.
      (2) All candidates operating fluoroscopic equipment without an approved operator readily available to assist with setup and operation of the equipment must also provide evidence of training with respect to the operation of the specific fluoroscopic system types to be used.
         (a) Approved operators include registered radiologic technologists and registered cardiovascular invasive specialists.
(b) This training must be completed under the direction of an individual approved to perform fluoroscopic equipment training.

(c) Individuals eligible for approval to conduct training includes registered radiologic technologists, registered cardiovascular invasive specialists, medical physicists, and health physicists.

(d) Vendor-provided training may satisfy portions of the training requirement if the approved trainer confirms required contents have been sufficiently addressed.

(e) All required training must be documented. Equipment-specific training is documented using the form “Documentation of Equipment Training for Physicians and Physician Extenders”.

2. Any exceptions to the above training requirements must be approved by the RSS.

3. Fluoroscopy shall not be used as a substitute for radiography but shall be reserved for the study of dynamics or spatial relationships or for guidance in spot-film recording of critical details.

4. The exposure rate used in fluoroscopy shall be as low as is consistent with the fluoroscopic requirements and shall not normally exceed 10 R/min (measured in air) at the reference location. Exceptions to this policy include fluoroscopic units equipped with a high-level option (provided that all requirements regarding high-level units are met) and radiation therapy simulator units.

5. Protective drapes designed to intercept scattered radiation may only be removed from the equipment for those procedures specifically granted a waiver for removal. The drapes must be reattached immediately upon completion of the procedure for which they were removed.

6. The hand of the fluoroscopist shall not be placed in the useful beam unless the beam is attenuated by the patient and a protective glove of at least 0.5 mm lead equivalent.

7. During fluoroscopy-based digital acquisition, special care shall be taken to limit patient exposure when, as is often the case, tube currents and potentials employed are significantly higher than those normally used in fluoroscopy.

8. Fluoroscopically-Guided Interventional Procedures
   a. A number of fluoroscopically-guided interventional procedures are in use that have the potential for extended fluoroscopic times. The cumulative radiation dose from these procedures can be sufficient enough to induce skin injury.
   b. A thorough equipment quality control program can help minimize these injuries.
   c. Including skin injury as one of the procedure risks in the patient consent form can inform the patient, prevent undue concern and promote early injury reaction and awareness.
   d. The U.S. Food and Drug Administration (FDA) has issued a public health advisory on the avoidance of x-ray induced skin injuries to patients. UNC Health Care adopts the principles of this advisory as a minimum injury prevention guide for all clinical services. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM063084

9. Total fluoroscopy time and reference air kerma (and other dose metrics, when available) are to be recorded.
   a. Actions required for significant reference air kerma levels include:
      (1) Any single procedure that results in a cumulative air kerma at the reference point of 5,000 mGy or greater to the same area of the body
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(a) Patient must be provided with the “Post Procedure Radiation Exposure Information Sheet”.

(b) Patient follow-up for deterministic radiation effect is recommended based upon patient specifics and provider judgement.

(2) Any single procedure that results in a cumulative air kerma at the reference point of 10,000 mGy or greater to the same area of the body
   (a) Patient must be provided with the “Post Procedure Radiation Exposure Information Sheet”.
   (b) Patient follow-up for deterministic radiation effect is required and must be documented. Recommended post-procedure follow-up time is 1 month.
   (c) Reference air kerma and procedure specifics must be reported to Radiation Safety Officer/ Radiation Safety Subcommittee.

(3) Any single procedure that results in a cumulative air kerma at the reference point of 15,000 mGy or greater to the same area of the body
   (a) In addition to the above requirements, this is considered an event reviewable under the Joint Commission Sentinel Event Policy.

J. Use of Hand-Held Dental Units

1. Hand-held dental units may be used only under a waiver granted by the RPS.

2. Approved devices may be used for dental exams under the following conditions:
   a. Operators must complete training provided by the manufacturer prior to use.
   b. A record of training must be retained for each operator.
   c. Personnel monitoring must be worn by operators during use of the device.
   d. The unit must be secured when not in use to prevent use by a non-authorized operator.
   e. If use requires angling the unit to a position that reduces operator protection, lead aprons or whole body protective barriers must be utilized.
   f. The back-scatter shield must be in place for use of the device.
   g. Each device must be used at a single registered facility unless registered as a mobile facility.

K. Pregnant or Potentially-Pregnant Patients

1. Special precautions, consistent with clinical needs, shall be taken to minimize exposure of the embryo or fetus in patients known to be or suspected of being pregnant.

2. It is the responsibility of the referring physician to determine the pregnancy status of patients of childbearing age, and to make a note in the chart describing the indication for the study and confirming that this was discussed with the patient. Exceptions to this include any study involving body parts above the abdomen or below the hips.

3. When the x-ray procedure does not include the abdomen or pelvis of the pregnant or potentially-pregnant patient, the abdominal region should be shielded with at least 0.25 mm lead equivalence whenever feasible, and the examination performed without regard to pregnancy.
4. When the x-ray procedure includes the abdominal region of the pregnant or potentially-pregnant patient, the examination shall not be performed without approval from the physician responsible for the procedure involving radiation.

5. Written informed consent should be obtained for all procedures involving direct exposure of the conceptus and/or whenever conceptus dose is likely to exceed 1 rem and shall be obtained whenever dose to the conceptus is likely to exceed 5 rem. Consent forms are available in English and Spanish.

6. Procedures involving the abdomen or pelvis with the conceptus in the field of view that are likely to deliver a conceptus dose greater than 1 rem include, but are not limited to, CT, fluoroscopy in excess of 1 minute, and radiographic procedures requiring multiple imaging (>3) of the conceptus region.

7. Although it is the responsibility of the referring physician to determine pregnancy status, those operating diagnostic x-ray equipment shall ask all patients of childbearing age whether or not they are pregnant and the date of their last menstrual period (this information is to be recorded prior to the procedure).

8. When pregnancy status is unclear, or when the date of the last menstrual period is greater than two weeks (14 days), a urine pregnancy test must be performed to exclude pregnancy, unless the delay necessary to perform the pregnancy test would jeopardize the patient’s health.

9. Radiation exposure must be used judiciously and kept to a minimum, and imaging techniques not involving radiation should be considered.

10. The imaging techniques used, such as fluoroscopic time, kVp and mA, as well as the number of images taken and the abdominal thickness measurements are to be recorded.

11. A radiation physicist should be contacted to assist with dose estimates. A formal dose calculation will be performed for procedures that are likely to deliver a conceptus dose in excess of 15 rem.

12. Radiation Safety is available for consultation at 919-962-5507, Monday – Friday 8 am to 5 pm, and after-hours and on weekends and holidays by calling 919-962-6565 and asking to have Radiation Safety paged.

L. Personnel Monitoring


2. According to this policy, all personnel who are likely to receive in excess of 10% of the occupational dose limits shall be provided with personnel monitoring devices.

3. Any radiation worker is pregnant or planning a pregnancy should review “Pregnant Employee - Conceptus Dose” (UNC Health Care Radiation Safety Manual Policy VII.3.). Those workers who choose to formally, in writing, declare their pregnancy or pregnancy plans shall be protected in accordance with the policy.

M. Quality Control

1. Image processing materials and techniques shall be those recommended by the system manufacturer or those otherwise tested to ensure the maximization of the imaging system.

2. Quality control methods shall be employed to ensure optimum results.
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3. X-ray systems shall be tested at least once per calendar year and in accordance with applicable accreditation requirements. Systems will be tested for compliance with performance and use criteria as specified by state and federal regulations as described in UNC Health Care Radiation Safety Manual Policy XII.3. - Quality Control of Diagnostic Imaging Systems.

4. The exposure rates to which patients are normally subjected during fluoroscopy shall be determined annually.

5. The shielding integrity of protective apparel must be evaluated at least one time per calendar year. Refer to Appendix B – “Guidelines for Surveying Protective Shielding Devices”.

6. The RPS has granted UNC Health Care a waiver from 10A NCAC 15 .0606(c) of the NC Regulations for Protection Against Radiation, relaxing the 30 centimeter minimum source-skin distance requirement for stationary x-ray units.

IV. Original Policy Date and Revisions


V. Comments

   For comments or questions about the contents of this policy, contact the Radiation Safety Officer at 919-962-5507.

Appendix A – Approved Policy Exceptions

Appendix B – Guidelines for Surveying Protective Shielding Devices