Clinical Practice Guideline: **Radiographic Quality and Safety Parameters**

Date of Implementation: **October 26, 2006**

Product: **Specialty**

Related Policies:
CPG 1: X-Ray Guidelines
CPG 58: Nasium & Vertex X-Ray Views
CPG 110: Medical Record Maintenance and Documentation Practices

The information presented in this Clinical Practice Guideline is not all-inclusive, however, it highlights pertinent radiographic (conventional and/or digital) industry and professional practice parameters and technical standards intended to ensure optimum diagnostic quality, while minimizing radiation exposure to patients, practitioners/technicians, and support personnel.

RADIATION SAFETY IN RADIOGRAPHY

Radiographs are recommended when clinical history and physical examination reveal signs and symptoms of potentially serious underlying conditions (red flags). But, "on its own, an isolated 'red flag' may have a high false positive rate for the diagnosis of underlying spinal pathology, such as cancer. For example, the presence of a solitary 'red flag' such as age over 50 years may not be sufficient to warrant taking spine radiographs". Clinicians should "combine sound medical judgment and the assessment of red flags when ordering radiographic examinations" (Corso et al., 2020).

Radiographic studies should be performed only when they are expected to yield clinically important information beyond that obtained from the history and clinical examination that can potentially alter patient management and improve patient outcomes. American Specialty Health – Specialty (ASH) has developed guidelines [*X-Ray Guidelines (CPG 1 – S)*] that may help inform the decision to obtain plain-film radiographs.

ASH Clinical Quality Administration and Clinical Quality Evaluation consistently apply the current body of knowledge to the decisions made regarding quality improvement initiatives, verification of medical necessity, and the credentialing and re-credentialing of practitioners for its networks. Information has been provided to American Specialty Health regarding the relative risks and benefits of performing an examination that requires exposure to ionizing radiation. Conclusions from these reviews are still valid and are consistent with information shared within this CPG and the *X-Ray Guidelines (CPG 1 - S)* clinical practice guideline.

A principle of value-based health care is that clinical interventions should be free from harm, or at the very least, the benefits of the intervention must substantially outweigh the risks. A known risk for ionizing exposure is the increased frequency of cancer beyond that occurring spontaneously and non-cancer diseases (i.e., cataracts, cardiovascular diseases). The current widely used theory on radiation accumulation is based on the linear no-threshold (LNT) model which in simple terms states: no dose of radiation exists without risk and that risk increases proportionally with dose. Currently, the argument remains that radiographic studies should not be considered in isolation but viewed as part of the patient's lifetime exposure. Ionizing radiation is a cumulative process that occurs from natural sources, such as sunlight, and decay of elements in our environment, as well as man-made sources, such as medical imaging (i.e., radiographs, computed tomography (CT) and nuclear medicine scans). It is therefore recommended by the International Commission on Radiological Protection (ICRP) and the Canadian Nuclear Safety Commission (CNSC), that in the absence of information pertaining to low-dose risks, to follow the "as low as reasonably achievable" (ALARA) principle. ALARA is not a dose limit, but a practice that aims to keep the dose levels as far as possible below the regulatory limit. (Corso, 2020) Clinicians therefore should strive for exposures that are aligned with the ALARA principle. This effort includes the use of appropriate equipment and technology (digital imaging, high speed screens), use of minimum necessary views, and appropriate assessment of "medical necessity" for radiological imaging.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

EDUCATION AND TRAINING OF PRACTITIONER

A practitioner performing radiographic examinations must have documented training and understanding of the physics of diagnostic radiography, experience with the equipment, demonstrate an understanding of the principles of radiation protection, knowledge of the hazards of radiation exposure to both patients and radiology personnel, and utilize appropriate radiation monitoring devices in the facility, as recommended by state and federal radiation control and regulatory agencies. The practitioner should also possess knowledge and competency in the principles and procedures of general radiography, screen-film combinations, and image processing (conventional and/or digital as applicable to the facility).

The practitioner should perform, interpret, and report radiographic examinations in accordance with nationally recognized standards of practice. The practitioner's continuing clinical education should include ongoing professional competency maintenance and

improvement as is appropriate to his/her practice and in accordance with applicable state law.

If a radiology technologist or qualified assistant performs radiographic examinations, the technologist/assistant must maintain state approved license/certification, as required.

QUALITY ASSURANCE, SAFETY, AND INFECTION CONTROL

- All imaging equipment, including hardware, imaging interfaces (imaging film/digital plates, cassettes, intensifying screens), software and a picture archiving and communications system (PACS) must comply with state and federal regulatory requirements and be in sound operational and mechanical condition and be working properly and reliably.
- Appropriate collimation and shielding (where applicable) should be utilized to limit exposure to the anatomical area(s) of interest and improve image quality by limiting scatter radiation. A properly centered and focused square-leaf collimator with light must be employed. Collimation must be used to exclude the eyes and other sensitive organs whenever possible and should not be any wider than necessary to view the region of interest. Evidence of collimation should be evident on at least three sides of the film. Masking, shuttering, or cropping should not be used as a replacement for beam restriction achieved through collimation of the x-ray exposure field size. Electronic masking should match the outer edge of the actual exposure field to document appropriate collimation. Masking should only cover the areas outside of the collimated exposure field and should never be used to cover anatomy that is contained within the exposure field.
- Because there is a decrease in radiation dose with digital imaging systems compared with conventional radiography, digital systems should be preferentially employed for imaging especially of known or suspected scoliosis.
- All imaging examinations involving ionizing radiation should be performed using technical factors offering the lowest radiation exposure to the patient that is consistent with image quality requirements.
- Pediatric patients are more sensitive to ionizing radiation than adults. Information regarding pediatric imaging best practices can be found at the Image Gently website: www.imagegently.org and the ACR website: (www.acr.org/-/media/ACR/Files/Practice-Parameters/rad-digital).
- Routine use of gonadal shielding is no longer recommended. The International Commission on Radiological Protection (ICRP) tissue-weighting factor for gonads has substantially decreased, from 0.25 in Publication 26 in 1977 to 0.20 in Publication 60 in 1990 and, most recently, to 0.08 in Publication 103 in 2007. Gonadal shields cannot protect against internal scatter, may be positioned incorrectly, may inadvertently move between positioning and exposure, may obscure the area of interest, and necessitate repeat imaging, and, if they cover the active automatic exposure control (AEC) region(s), may substantially increase

radiation exposure. Patient shielding may be an effective means of alleviating patient anxiety. In those cases, the priority should be to ensure that the shielding device does not adversely impact the quality of the examination. One general technique that can help ensure that shielding does not adversely impact the quality of the examination is to ensure the shield is not within the bounds of the collimation light.

- Use the highest kVp within the optimal range for the position and part, coupled with the lowest milliampere-seconds (mAs) needed to provide an adequate exposure to the image receptor.
- Use of AEC modules is indicated when the AEC has been calibrated to the type of image receptor to provide consistent exposure to the image receptor. The use of AEC should be carefully monitored when used in conjunction with appropriate shielding. When combined, a beam absorbing material such as lead should not routinely lie within the primary beam field of view.
- All facilities producing radiographs should have policies and procedures for appropriate shielding of patients and healthcare workers.
- Monitoring exposure of healthcare workers with radiation badges is strongly encouraged to recognize when the dose limit is exceeded and there is a need to reduce exposure and safeguard the worker's health. If individual monitoring is not feasible, radiation exposure should be passively measured with a dosimeter placed near the X-ray source.
- Facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. Over-the-Counter pregnancy test kits may be considered in this process. Pregnancy, especially in the early trimesters, significantly impacts the benefit: risk ratio and the decision whether to obtain radiographs needs to be carefully considered. If a decision is made to obtain radiographs of a pregnant or a potentially pregnant patient, a written informed consent should be obtained prior to performing the procedure.
- Notices regarding pregnancy should be posted in compliance with all applicable state regulatory requirements, and include language such as, “If it is possible that you might be pregnant, notify the physician or other staff before your x-ray examination.” If patients frequent the practice that do not speak English well, consideration for language-appropriate notices in addition to English language notices should be given.
- Facilities providing radiographic services should have documented policies and procedures related to quality control, patient education, infection control, and safety.
- Implement a comprehensive quality assurance program that involves all aspects of quality control and continuous quality improvement, including repeat analyses specific to the digital imaging system. The quality control program should include documented protocols and procedures for maintaining imaging equipment;

maintenance and cleaning of film processors; and orientation and training of staff. All applicable state regulatory requirements must also be maintained.

- The use of DICOM (ACR– National Electrical Manufacturers Association Digital Imaging and Communications in Medicine) modality work lists is recommended to help ensure the quality and accuracy of the information captured in the DICOM header.

SPECIFICATIONS OF RADIOGRAPHIC EXAMINATION

- Be familiar with the specific exposure indicator/index (EI) standards for equipment and with the standardized EI as it becomes available in new and upgraded equipment used for digital radiography.
- Effectively use the EI and deviation index to determine whether adequate exposure has reached the image receptor.
- Regularly evaluate EI values, along with image quality to determine whether the digital image meets quality standards.
- Digital radiographic devices must provide images that conform to the DICOM standard computed radiography (CR) or direct radiography (DR) service class objects. These objects' header fields specify information such as accession number, patient name, identification number, date and time of examination, name of facility or institution of acquisition, type of examination, patient, or body part orientation (e.g., right, left, superior, inferior), amount and method of data compression, and total number of images acquired in the study.
- Use anti-scatter grids when appropriate (e.g., when body parts measure greater than 12cm in thickness). Scattered radiation reduces contrast in radiography, limiting the available dynamic range of x-ray intensities at the beam exit side of the patient.
- In digital radiography, excessive exposure to the detector can produce high-quality images with improved noise properties. Unless there is an understanding that these higher quality images come at the cost of increased patient exposure and strategies are in place to control patient exposure, a radiologic practice may experience "exposure creep." A method to prevent exposure creep is to develop validated radiographic techniques as a function of patient size for all performed examinations and perform regular quality control analysis. Technique charts should encourage the use of appropriate automatic exposure control (AEC) settings (single cell versus a combination of multiple AEC cells) for most of the body radiographic examinations. The AEC system is designed to deliver calibrated and reproducible doses to the image receptor across a wide range of operating conditions, including x-ray beam quality and patient size. Often these factors are entered into the anatomical programming of x-ray generator controls. If the technologist uses these programs, the facility is very likely to use appropriate radiographic technique factors with the appropriate level of radiation exposure. Consistent and optimal AEC performance is critical to radiation dose management and image quality.

- Objects which may produce unacceptable artifacts (e.g., jewelry, hair ornaments) should be removed before exposure is made. A supply of clean, appropriately sized gowns should be available to avoid clothing artifacts such as zippers and buttons.
- All radiographic studies should be permanently imprinted with patient's complete name; date of birth or age; facility name and location; and date of the examination. The side (right or left) of the anatomic site radiographed should be permanently labeled (e.g., use of Mitchel marker).
- All facilities performing radiography should have written protocols for standard views of each anatomic area that will be imaged. These should be designed to optimize diagnostic information while minimizing radiation exposure.
- All facilities performing radiography should have technique charts, or protocols in generator memory, for all anatomic parts, listing exposure factors that will reliably produce diagnostic-quality images of patients of different sizes, to minimize the need for repeat exposures. Repeat rates should be part of the routine quality control process.
- Determining proper technique charts for standard examinations exposure (technique) charts are part of the standard of care expected by the Joint Commission and are required by regulations in many states. It is necessary to check state and/or local regulations for any specific requirements. Computation of estimates for entrance skin exposures for these charts may also be required.
- Because of the wide latitude of digital image receptors and the availability of image processing to alter the brightness and contrast of images, the visual appearance of images can be made similar over a wide range of acquisition techniques. The primary effects of modifying an acquisition technique are changes in:
    1. The level of noise in the image
    2. The exposure duration and potential for patient motion artifacts
    3. Patient radiation exposure, and
    4. Potential artifacts (in digital radiography) related to detector saturation and image lag.
- All radiographs should be reviewed for positioning and diagnostic quality at the facility before the patient is released for the day. X-rays must be of diagnostic quality.
- All facilities performing radiography should have protocols for the standard view or views of each anatomic area of interest. These should be designed to optimize diagnostic information while minimizing radiation exposure.
- Supplemental views should be obtained only when clinically indicated or when abnormal findings are found on an initial study.
- Opposing (orthogonal) views are generally required for a diagnostic assessment when choosing to image any area; single plane views are usually insufficient.

- Radiographic examinations of the spine or extremities should completely demonstrate the designated regions, or the levels of clinical interest in a limited examination.
- Because scoliosis examinations are common in children, the digital image receptor must provide an efficient method to generate images up to 36 inches in length without doubly exposing some sections of the patient's anatomy. Use of newer technology, such as slot scan units for orthopedic imaging, may further reduce dose associated with these examinations.
- Appropriate immobilization and assistance procedures should be available to ensure that images of diagnostic quality can be obtained in patients who are unable to cooperate or unable to be positioned in the usual manner due to age or physical limitations, while avoiding unnecessary irradiation of health care workers.

RADIOGRAPHIC REPORTING DOCUMENTATION STANDARDS

The written or electronic request for a Radiograph should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation. Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination (American College of Radiology, 2022).

All radiography examinations must include a documented interpretation of the findings (radiology report). This report must be maintained as a permanent part of the patient's medical record, and include information, such as:

- Patient name or other identifier;
- Patient's date of birth or age;
- Patient's gender; Name(s) of ordering physician(s) or other health care provider(s). If the patient is self-referred (a patient who seeks medical care without referral from a physician/health care provider), that should be stated;
- Facility name and location;
- Date of the examination;
- Time of the examination, if relevant (e.g., for patients who are likely to have more than one of a given examination per day);
- Relevant clinical information and diagnosis;
- Description of the studies (anatomical location and views taken);
- Any known significant adverse event involving the patient that occurred in relation to performance of the study should be briefly noted in the impression;
- Electronically record exposure techniques, EI and dose data with the radiographic image to allow for assessment and refinement of technique selection practices. Details related to image acquisition, such as tube potential (kV), tube current (mA),

exposure time, beam filtration, source image distance, the International Electrotechnical Commission (IEC) 62494-1 detector exposure indicator (EI), target exposure index (EIT), deviation index (DI), and organ-specific postprocessing algorithm employed, should be recorded in the DICOM header. These elements should be exportable using the DICOM Structured Report;

- Report should include appropriate anatomic, pathologic, and radiologic terminology to describe all findings;
- The report should, when appropriate, identify factors that may compromise the sensitivity and specificity of the examination;
- The final report is the definitive documentation of the results of an imaging examination or procedure. Use of abbreviations or acronyms should be limited to avoid ambiguity;
- The final report should be completed in accordance with appropriate state and federal requirements. Electronic or rubber-stamp signature devices, instead of a written signature, are acceptable unless contrary to state law, if access to such devices is secure;
- When feasible, a copy of the final report should accompany the transmittal of relevant images to other health care professionals, when such images are requested.
- A copy of the final report should be archived by the imaging facility as part of the patient's medical record and be retrievable for future reference. Retention and distribution of these records must be in accordance with state and federal regulations and facility policies;
- Limitations impacting the ability to read/interpret radiographic findings should be identified (e.g., artifacts, poor quality of film, technical factors);
- The report should address any specific clinical questions; if there are factors that prevent answering the clinical question, this should be stated explicitly;
- Comparison with relevant examinations and reports (e.g., previous x-rays, CT, MRI) should be included in the radiologic report when appropriate;
- Impression should include a precise differential diagnosis, any significant patient reaction, and recommendations for follow-up or additional diagnostic studies to clarify or confirm the impression when appropriate;
- Person providing the interpretation of the study must be identified on the report;
- Inclusion of the following items is encouraged:
    - Date of dictation
    - Date and time of transcription

For more detailed information regarding Communication of Diagnostic Imaging Findings, see the American College of Radiology practice parameter for communication of diagnostic imaging findings located at www.acr.org.

SPECIFICATIONS OF EQUIPMENT

- The diagnostic radiographic equipment and facility should meet all applicable federal and state radiation standards.
- Recognize image artifacts and prevent future artifacts by properly maintaining and acquiring service for the digital radiography equipment.
- To ensure the enterprise-wide availability of features and performance when purchasing digital radiographic and connected equipment, consideration of the manufacturers' statements of conformance with the current ACR– National Electrical Manufacturers Association Digital Imaging and Communications in Medicine (DICOM) standard is strongly recommended.
- The use of the DICOM "DX" service class object is recommended instead of the more limited "CR" object for digital radiography.
- It is recommended to use DICOM grayscale soft-copy presentation state (GSPS) objects to transmit annotations, shutter, and display lookup tables (LUTs). Where GSPS is not available or not supported by a picture archiving and communication system (PACS), the use of a values-of-interest lookup table (VOI-LUT) within the CR or DR service class object is suggested.
- Presently, new Digital Radiography systems and upgraded software versions for existing equipment are incorporating the Electro-technical Commission (IEC) standard. In addition to the traditional exposure index, a deviation index is reported that describes how the exposure index deviates from a target value. Users should review the target values for all views of all body parts that the system will be used to image. Target values should be selected to minimize the exposure to the patient while providing diagnostic images (i.e., with sufficiently low noise) for interpretation.
- All digital software and image production hardware should be in proper working order, serviceable with new (current) parts and possess up to date software versions to ensure optimal function and quality.
- For non-digital (analog) imaging, automated film processing is preferred. Carefully controlled temperature and regularly scheduled processor maintenance should be included in a quality control program. A constant time and temperature should be maintained for manual processing. The chemicals must also be replenished appropriately.
- For digital imaging, image processing can be divided into two (2) parts.
    - Preprocessing is performed on the raw output of the digital detector and accounts for various performance and engineering deficiencies of the image receptor.
    - Postprocessing is used to optimize the contrast, sharpness, and latitude of the image to be displayed at the radiologist review workstation.

For detailed information including but not limited to information about image processing for digital imaging, see the American College of Radiology practice parameter for digital radiography located at www.acr.org.

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