



# Guidelines for Radiation Safety

*Created in 2012*

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*The guidelines set forth herein and approved by the CLEAR Scoliosis Institute Board of Advisors on June 14<sup>th</sup>, 2012, have been created in accordance with the radiographic safety guidelines as set forth by the American Nuclear Society, the Radiological Society of North America, the American College of Radiography, the Health Physics Society, the International Atomic Energy Agency, the Pan American Health Organization, and the World Health Organization. For additional information on these guidelines, please refer to the IAEA Safety Standards Series: Radiological Protection for Medical Exposure to Ionizing Radiation, No. RS-G-1.5.*

## Introduction

The benefits of radiography to the practicing clinician are considerable. However, due care must be taken to protect patients from unnecessary radiation exposure. In all aspects, the potential risks of radiation exposure must outweighed by the potential benefits, and exposure to radiation from diagnostic imaging must follow the ALARA (As Low As Reasonably Achievable) standard. The purpose of this document is to provide the doctor of chiropractic involved in the treatment of scoliosis with helpful guidelines to assist them in areas of clinical decision making concerning x-ray exposure, with a particular emphasis on the pediatric patient population. These are only guidelines and are not intended to serve as regulations or standards of practice, nor imply any exertion of control nor legal standard for any instance. Deviation from the practices & protocols outlined in this document may be necessary in individual clinical scenarios, and the decision-making ability of the primary care provider involved in each case should not be restricted unnecessarily. In instances where deviation from established guidelines is necessary, it is recommended that the patient's informed consent documenting their understanding of the extenuating circumstances is obtained by the treating doctor.

According to the most recent information from the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the WHO, 2.5 billion diagnostic exposures to ionizing radiation are performed annually worldwide. 78% of these exposures are medical x-rays, 21% are dental x-rays, and the remaining 1% are due to nuclear medicine techniques. The annual worldwide average exposure from medical imaging is 0.4 mSv (40 millirem). In the United States, this ranges from 1.3 mSv (130 millirem) at the upper levels of healthcare down to only 0.02 mSv (2 millirem) at the lower levels. The average exposure that one person receives from all sources in one year, according to the American Nuclear Society, is 6.2 mSv (620 millirems).

The basic principles of protection for medical exposures are summarized in the IAEA Safety Standards as follows:

*“Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.”*

*“The doses from medical exposures should be the minimum necessary to achieve the required diagnostic objective or the minimum to the normal tissue for the required therapeutic objective.”*

In accordance with these principles, the CLEAR Scoliosis Institute has developed the following guidelines to protect patients from unnecessary radiation exposure and to minimize exposure from diagnostic radiographs that are considered necessary by the treating clinician, and also to provide guidelines to differentiate between the two. As stated by the IAEA, the medical practitioner has the primary task and obligation of ensuring patients' overall protection and safety in the prescription and delivery of medical exposure.

The x-ray safety protocols presented apply to both convention radiography (CR) and video fluoroscopy (VF, commonly referred to as DMX or Digital Motion X-Ray) techniques.

## **BASIC PRINCIPLES OF X-RAY SAFETY**

### **Inspection and compliance monitoring**

All CLEAR clinics must abide by state regulations concerning medical imaging and the use and possession of ionizing radiation equipment. A certificate or document attesting to this fact must be prominently displayed in a public location.

On-site inspection of the x-ray unit(s) must be performed at least once every two years. Issues identified through the course of the inspection must be addressed and, in the case of those that required corrective action, a subsequent re-evaluation must be performed.

### **Patients right to informed consent**

All patients must have the right to request information about x-ray safety, and this information must be on hand for the clinician to provide to the patient. This information must be consistent and accurate with the x-ray safety information approved by the CLEAR Scoliosis Institute.

### **Adequate training**

All CLEAR clinics must ensure that the staff members involved in the process of obtaining diagnostic imaging have adequate training & experience to perform the required tasks.

### **Record keeping**

All CLEAR clinics are required to maintain good record keeping practices in regards to radiography. The type of imaging procedure performed, the purpose of the procedure, the patient who received the imaging, and the date that it was performed must all be recorded. Additional information, such as the time of day that the x-ray was taken, the estimated individual and cumulative doses, and the outcome of & clinical data obtained from the procedure, must also be recorded.

### **Re-taking films**

When it is necessary to re-take a film, the reason for the re-take must be recorded and the patient must be informed as to the necessity of the repeat procedure. The estimated individual and cumulative doses must also be updated.

## Research purposes

As stated by the IAEA, exposure to ionizing radiation for research purposes must be carried out in accordance with the provisions of the Helsinki Declaration and the guidelines for its application as given by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO). All CLEAR clinics participating in data collection for research purposes must obtain prior informed consent from all patients.

## Justification and optimization of imaging

*“The basic aim of the optimization of patient protection in diagnostic imaging is to maximize the benefit over the harm, while taking into account social and economic circumstances. Since patients are deliberately exposed to radiation sources, the optimization of protection can be complex and does not necessarily mean the reduction of doses to patients, as priority has to be given to the acquisition of reliable diagnostic information.”* (IAEA, Section 2.44)

In preparing a treatment plan for an individual, the number of expected CR & VF imaging procedures that will be undertaken must be established, and the cumulative radiation dose estimated and explained to the patient as part of the informed consent process.

## Radiation and pregnancy

According to *Principles of Patient Radiation Protection & ALARA* by Nicholas Joseph Jr., RT(R) and Jeffrey Phalen MD;

*It is the responsibility of any person who orders x-rays of a female of childbearing years to screen them for potential pregnancy. This responsibility is also extended to the technologist who should inquire prior to any x-ray exposure. Furthermore, the institution is required to post warnings requesting female patients to declare their pregnancy. These warnings must be posted in areas such as the preparation and waiting areas of the department where the patient is highly likely to see them. In centers that service multiethnic groups the warning should appear in several of the most common languages that are spoken.*

*It is required that all institutions accredited by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) must monitor doses from diagnostic imaging procedures. The Center for Devices and Radiological Health (CDRH) recommends that a diagnostic imaging facility maintain records of radiation doses received by a patient. Although it is not a common practice for radiographers to record the number of films taken and the number of attempted radiographs taken on each patient, most institutions estimate dose for each type of imaging study and average calculated repeat rates.*

*Radiation dose to the fetus of less than 1 rad/rem is considered negligible or to have no realistic effect; however at greater than 1 rad/rem the risk is greater and concerning. NCRP report No 54, Medical Exposure of Pregnant and Potentially Pregnant Women, states that the risks associated with exposure to 5 rad is negligible when compared to other risks associated with pregnancy. The concern with irradiating a pregnant woman is "should" the pregnancy be terminated because of exposure. There are at least three considerations that interplay in the decision: 1) the exact gestational time at exposure must be known, 2) a reasonably accurate estimated calculation of fetal dose, 3) a general understanding of how the patient feels towards pregnancy termination based on their age and health. What is considered in terms of fetal dose is that the risk of malformations increases greatly above 15 rad. A woman that receives 25 rad within 4 weeks of conception should consider abortion, whereas 5 rad in the third trimester would rarely be a reason for termination of pregnancy.*

*Certainly the most vulnerable time of embryo/fetus irradiation is the first trimester. Research supports the theory that any harmful effect to the fetus during the first two weeks of gestation (a time which the female may not know she is pregnant) is an all-or-none effect. The effect produces prenatal death which is spontaneous abortion of the embryo. Animal research correlation points to approximately 10 rad are required in the first 2 weeks to cause the spontaneous abortion rate to increase 0.1%. The normal spontaneous abortion rate is greater than 25% of all pregnancies. **Based on these statistics the 10 day rule was developed, which states that the best time to image females is in the 10 day period following the onset of menstruation; however, this rule has largely been abandoned. The ICRP uses the 28 day rule since the effect on the embryo is dose dependent and all-or-none not favoring abortion.***

According to the CDC, "Most researchers agree that babies who receive a small dose of radiation (equal to 500 chest x-rays or less) at any time during pregnancy do not have an increased risk for birth defects. The only increased risk to these babies is a slightly higher chance of having cancer later in life (less than 2% higher than the normal expected cancer risk of 40 to 50%)."

Despite the low risk inherent in radiation exposure during pregnancy, it is the official position of CLEAR that CR & VF procedures are not to be performed on women who are pregnant or have reason to believe they may be pregnant. However, we do not recommend implementation of the 10-Day Rule; rather, we recommend adoption of the 28-Day Rule as implemented by the ICRP.

### **Radiation and pediatric patients**

Whenever possible, annual radiation exposure to a pediatric patient (below 18 years of age) from medical imaging is to be kept below 5 mSv (500 millirem), in accordance with established EPA radiation safety guidelines for medical imaging. If the cumulative annual dose is expected to exceed or is found to have exceeded this amount, the parents/legal guardians are to be notified of this fact.

## Dose Reduction Strategies

### Radiographic Technique: Setting kVp and mAs

According to *Principles of Patient Radiation Protection & ALARA* by Nicholas Joseph Jr., RT(R) and Jeffrey Phalen MD;

*"In order for the radiographer to produce high quality diagnostic images, they must achieve a delicate balance between exit radiation, photoelectric effect, and Compton scatter. In the low kVp range, the physics of ionizing radiation favors the photoelectric effect; at high kVp the balance is shifted to favor exit radiation and Compton scatter. The radiographer tries to keep the exposure balance tilted towards a greater proportion of exit radiation and scatter in compliance with the thesis called ALARA. This means as high a kVp as is reasonable to achieve the high quality radiographic detail to render clinical diagnostic differentials. In this manner the photoelectric effect and patient dose photon is kept to a minimum.*

*"A simple radiography rule of thumb is that increasing the kVp by 10 at 80 kVp, with compensatory decrease in the mAs, will decrease the intensity by about 25%. A compensatory decrease in the mAs at 60 kVp with a 10 kVp increase results in a 15% decrease in the intensity of radiation. We see that if the initial energy of the x-ray beam selected is 75 kVp having an intensity of 100 mR, then the intensity of the beam at 90 kVp is, assuming all other factors remain the same will be 144 mR. **Thus the kVp intensity formula tells us that increasing the kVp with all other factors remaining the same will also increase the intensity of radiation.***

*"If a change in kVp necessitates optimizing to produce an equivalent radiographic density, a 50% decrease in the mAs will be required for each 15% increase in kVp.*

*"There are three reasons why increasing the average energy of the photons cause a reduction in intrinsic patient dose: 1) some of the scatter radiation that is absorbed by the patient at a low kVp will now have sufficient energy to exit, 2) because the average photon energy is increased there is a decrease in the relative number of primary photons that undergo the photoelectric effect, instead they will become exit radiation, 3) more exit radiation is made available to effect radiographic image density and contrast so that the mAs can be decreased, which is a reduction in patient exposure."*

Based upon this information, we recommend that all CLEAR doctors instruct their radiographic staff to take films with kVp as high as possible (and hence the mAs as low as necessary to produce the highest-quality diagnostic images), in order to achieve a reduction in patient dose.

### Aluminum Foil Filtration

According to *Principles of Patient Radiation Protection & ALARA* by Nicholas Joseph Jr., RT(R) and Jeffrey Phalen MD;

*Studies show that without beam filtration low energy photons will be absorbed by the patient contributing nothing to the radiographic image. Low energy photons can be attenuated from the useful beam prior to it reaching the patient. In fact, a beam that is filtered will reduce the entrance skin*

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exposure significantly. In a study by Trout and colleagues, it was calculated that using an 85 kVp beam with an intensity of 1225 mR without filtration was reduced to 287 mR with 3 mm aluminum filtration without compromising image quality. This is about a 77% reduction in the exposure by simply applying a filter to the primary beam. After filtration, the x-ray beam is said to be “hardened” meaning its average energy is increased giving the beam a higher quality.

<b>Exposure Dose To The Skin For Comparable Density Radiographs of a Pelvic Phantom (18 cm Thick) With Various Thicknesses of Aluminum Filtration</b> Trout, E.D., Kelly, J.P., and Cathey, G.A.		
<b>Aluminum Filtration</b>	<b>60 kVp</b>	
	<b>Exposure Dose To Skin (Milliroentgens)</b>	<b>Percent Decrease in Exposure Dose</b>
None	2,380	-
0.5 mm	1,850	22
1.0 mm	1,270	47
3.0 mm	465	80

Chart from Trout, E.D., Kelly, J.P., and Cathey, G.A., “The use of filters to control radiation exposure to the patient in diagnostic roentgenology,” American Journal Roentgen., 67,942,1952.

*Trout and colleagues demonstrated that beam filtration significantly reduces patient skin dose, and also demonstrated that filtration above 3.0 mm aluminum can significantly reduce the intensity of the primary beam requiring an increase in the exposure technique to compensate for lost photons.*

**Therefore, filtration greater than 3.0 mm aluminum equivalency is not recommended by the NCRP.**

*Filtration removes mainly those photons of less than 40 keV effectively hardening the beam. The quality of the x-ray beam is therefore improved because it increases the half value layer (HVL) of the beam. NCRP regulations specifying filtration are in HVL units because this is the biomedical engineering standard for measuring and certifying beam filtration as required by the FDA. The halve-value-layer (HVL) is defined as that thickness of a given material that will reduce the intensity of a radiation beam to one half its original value(s). For energies used in diagnostic imaging up to three half-value-layers may be required by the FDA. When testing the quality of beam filtration, measuring the HVL is the testing standard.*

We recommend, in accordance with the FDA Total Filtration Mandates for X-Ray Equipment for radiographic tubes, at least 2.5 mm of aluminum foil should be used for films above 70 kVp, at least 1.5 mm for 50-70 kVp, and at least 0.5 mm for films captured below 50 kVp.

### **P-A versus A-P Scoliosis Films**

According to the American College of Radiography, PA positioning is preferred for scoliosis evaluations.

According to Levy *et al* (*Spine* 1996):

*“If the anteroposterior view was replaced by the posteroanterior view, a three- to sevenfold reduction in cumulative doses to the thyroid gland and the female breast would be achieved, yielding three- to fourfold reductions in the lifetime risk of breast cancer and a halving of the lifetime risk of thyroid cancer.*

*“The cancer risks from full-spinal radiographs for scoliosis are not negligible and can be reduced from one half to three quarters if the anteroposterior view is replaced with the posteroanterior view.”*

### **Shielding**

We recommend gonadal shielding be employed on scoliosis films, and a lead apron be worn for cervical films.

### **Patient Positioning by another individual**

The FDA does not allow an employee to be designated to hold a patient in order to capture an x-ray. They recommend that the parent or family member provide assistance. We recommend that a lead apron be worn by the family member if this is necessary.

### **Timeline for recent scoliosis films taken by other sources**

We recommend that scoliosis films taken within 6 weeks are appropriate for use in consultation, patient screening, and evaluation purposes. For treatment purposes, we recommend the scoliosis film should be dated no more than 2 weeks prior to the initiation of treatment. These guidelines are arbitrary and may be modified at the doctor’s discretion.



## Standardized information for patient education

*Below is suggested information that may be used for patient education purposes.*

*It is vital that CLEAR doctors report similar numbers when reporting exposure rates from the CLEAR x-ray series.*

There is a great deal of misinformation and confusion amongst the general public regarding x-ray safety.

Much of the current fear of diagnostic imaging revolves around computerized tomography (CT) and mammograms. These procedures involve amounts of radiation exposure that are significantly higher than the CR & VF protocols used in the CLEAR Scoliosis Clinics.

The U.S. Department of Energy estimates that the exposure amount for one mammogram image is 1.4 mSv (140 mrem). A typical mammogram includes three images, so the total exposure would be approximately 4.2 mSv (420 millirem). According to the Health Physics Society and the American Nuclear Society, a typical CT scan exposes the patient to 10 mSv (1,000 millirem).

By contrast, the eight x-rays taken as part of a standard CLEAR spinal examination total 1.51 mSv (151 millirem). This is approximately one-quarter of the radiation exposure the average individual receives from environmental sources in one year.

The standard radiographic examination as set forth by the CLEAR Board of Advisors consists of the following:

- Five Cervical Spine x-rays (Lateral Cervical Neutral, Lateral Cervical Flexion, Lateral Cervical Extension, A-P Open Mouth, and Base Posterior) are taken, totaling 0.09 mSv (9 millirem).
- One Thoracic spine X-ray (14" by 17" P-A scoliosis view) is taken, which is 0.02 mSv (2 millirem).
- Two Lumbar spine x-rays (Lateral Lumbar and A-P Lumbar) are taken, totaling 1.4 mSv (140 millirem).

The total amount of radiation from the initial examination is then 1.51 mSv (151 millirem).

Two additional lateral bending thoracic spine x-rays may be taken for research purposes, or to evaluate the flexibility of the curve. This adds 0.04 mSv (4 millirem).

Two additional cervical spine x-rays (APOM and a stress x-ray) may need to be taken (based upon the individual patient need and the clinical decision-making of the treating doctor) to evaluate the effect of the treatment, adding an additional 0.04 mSv (4 millirem).

**Source: Wall BF, Hart D: Revised radiation doses for typical x-ray examinations. *British Journal of Radiology* 1997;70:437-439.**

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We recommend that the post-treatment radiographic examination should exclude the lumbar x-rays unless:

- 1) The patient requests the additional views.
- 2) There was a greater than 50% loss of curve in the lumbar spine on the pre-treatment x-ray.
- 3) There is clinical or radiographic evidence of a retrolisthesis or spondylolisthesis.
- 4) The patient has active symptomatology in the lumbar region.
- 5) The clinician feels it is necessary to compare the standing scoliosis view to the seated in order to evaluate the ability of the spine to resist axial compression.
- 6) The clinician is evaluating the effect of an individualized, patient-specific treatment plan and feels that the information from the lumbar x-ray is clinically necessary to evaluate the efficacy of that plan.

The post x-ray exam without the lumbar x-rays totals 0.11 mSv (11 millirem).

The clinician may choose to exclude the cervical spine series on the post x-ray exam, reducing the total to only 0.02 mSv (2 millirems) for the post-treatment thoracic spine x-ray.

Typical cumulative dose for the initial 8 view exam, 2 views for research, 2 views for evaluation of the treatment plan, and the 6 view post exam (excludes the lumbar x-rays): 1.7 mSv (170 millirem)

EPA annual limits for radiation exposure from medical imaging for children under 18: 5.0 mSv (500 millirem)

EPA annual limits for radiation exposure from medical imaging in adults: 50 mSv (5000 millirem)

There is no evidence to suggest that radiation below these levels has any negative health effects whatsoever. In addition, the radiation hormesis theory suggests that low doses of radiation may in fact have a beneficial effect upon health.

Based upon these figures, a pediatric patient will not exceed the EPA safe limits for radiation exposure if they undergo the complete CLEAR Intensive Care program two times in one year.

If a pediatric patient undergoes the CLEAR Intensive Care program three or more times in one year, the parents/guardians must be notified that the patient is at risk of exceeding the safe limits. The risk can be reduced by excluding lumbar x-rays from follow-up exams.

It should be noted at this point that researchers at the Vanderbilt University School of Medicine reported in 2011 that DNA is capable of repairing radiation-induced DNA damage. This contradicts the previously-held belief that radiation damage could *not* be repaired, and doses were cumulative throughout life. For this reason, if it is possible to increase the time intervals between x-ray exposures, this would be of benefit to the patient.

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There appears to be little to no danger that an adult patient would experience any adverse health effects whatsoever from radiation exposure associated with the CLEAR Scoliosis Treatment protocols. To do so would require that the patient undergo the complete CLEAR Intensive Care program 29 times in one year.

*“Below 100 mSv (10,000 millirem), risks of health effects are either too small to be observed or are nonexistent.”* -Radiation Risk in Perspective: Position Statement of the Health Physics Society, Revised August 2004.

#### **Additional information about interim x-rays (APOM, stress views, and training effect films):**

Occasionally, interim films may be necessary to evaluate the patient’s response to care prior to the final examination. These films serve as “checkpoints” to ensure that effectiveness of the prescribed care plan, and also aid in providing the patient with accurate prognostic information regarding their expected results.

The purpose of the interim APOM film, taken after the 3<sup>rd</sup> treatment session, is to obtain radiographic confirmation of the correction of the upper cervical subluxations detected on the initial APOM film. Due to the large concentration of mechanoreceptors in the upper cervical area, failure to obtain correction in this regard could have a negative effect upon the patient’s response to care. If the interim APOM film fails to demonstrate the expected correction, the treating doctor must re-evaluate the adjusting methods and alter the care plan accordingly in order to achieve the expected outcome. Additional interim APOM films may be necessary in this instance, according to the doctor’s clinical judgment. In this case, the reason for the additional films must be explained to the patient and informed consent obtained.

The purpose of the lateral cervical “stress” film and the thoracic spine “training effect” film is to serve as a “crystal ball” to aid in the formulation of an accurate prognosis. By placing various weights, cantilevers, or straps on the patient according to their individual posture and spinal configuration, and allowing the body to react to these strategically-placed forces, the goal is to stimulate neuromuscular proprioceptive re-training of the involved motor-sensory feedback circuits. Also, a thoracic spine x-ray may be taken while the patient is positioned in the Scoliosis Traction Chair with pads and straps positioned to de-compress, de-rotate, and de-translate the spine back to midline, the purpose again being to stimulate neuromuscular re-education, and also to aid in bony and soft tissue deformation with the addition of whole-body vibration therapy. As these goals are long-term goals which will not be realized in a two-week timeframe, but rather require continuing and ongoing effort on the part of the patient’s home rehabilitation protocol, it is vital that the doctor understand what the effect of these various therapies will be upon the patient before they leave the office. If additional interim x-rays are necessary to properly evaluate the therapeutic benefit to the patient, the reason for the additional films must be explained to the patient and informed consent obtained.

Radiation exposure from fluoroscopic imaging must be recorded in a document such as the radiologist report or the patient's chart. It is the responsibility of the fluoroscopist to administer patient dose in compliance with ALARA during imaging. Intermittent beam on-off-on off exposure is one of the best ways to reduce patient exposure. The FDA mandates that controls on the console remind the fluoroscopist when a significant dose to the patient has been reached. Specifically, a 5 minute cumulative timer with audible sound must be operational when using fluoroscopy. The audible tone reminds the physician that a reasonable exposure dose has been administered. It also serves as a warning that the exposure time to a local area cannot be taken for granted as literature shows several examples that local radiation burns are possible from fluoroscopic imaging procedures. **Under no circumstance should the time of exposure to a local area exceed 5 minutes.**

The study below illustrates the fact that, despite the lower-image quality of most video fluoroscopy units when compared to conventional radiography, Cobb angle can be read accurately on VF units, with a significant (92%) reduction in the amount of radiation exposure.

Comparison of conventional full spine radiographs and fluoroscopic scanning method in young patients with idiopathic scoliosis

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### Abstract

**PURPOSE:** Evaluation of low-dose full spine radiographs using fluoroscopic images for the assessment of the Cobb angle measurement in patients with scoliosis.

**MATERIAL AND METHODS:** Twenty-one consecutive patients (aged 10 - 27 years, mean age 14 years) with a conventional full spine examination (film speed class 800) underwent a follow-up exam using digital pulsed fluoroscopy (Multi Diagnost 4, Philips Medical Systems, Eindhoven, The Netherlands). **RESULTS:** The mean DAP values for conventional imaging was 94.9 cGy x cm (2) and for fluoroscopy 7.8 cGy x cm (2), respectively. A significant dose reduction of 91.8 % (CI 91 % to 95 %) was calculated. The average absolute angle difference between the observers was found to be 2.7 degrees for conventional imaging and 2.4 degrees for the fluoroscopic method. Interobserver standard deviation of 2.9 degrees was lower than the 5.3 degrees for conventional images. Image quality was better in the conventional images.

**CONCLUSION:** Using the scanning method, we could achieve a mean reduction of the radiation dose of 92 %, while the accuracy of the Cobb angle measurements was comparable for both techniques despite of reduced image quality of digital fluoroscopy.