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To: Virtua Surgeons and Physicians Utilizing X-ray Fluoroscopy

From: Daniel J. Januseski, M.S., RSO, CDMP

Subject: Education and Competency in the Safe Use of Fluoroscopic C-arm Units

Dear Physician Colleague,

Virtua is obligated by the regulations of the NJDEP and the standards set by the Joint Commission to ensure the safe use of ionizing radiation in the healing arts by licensed practitioners. As patients and families become increasingly aware of the risks of medical radiation, we must ensure that all users of these diagnostic tools are knowledgeable and comfortable with their operation.

As recently published in the Joint Commission’s Sentinel Alert #47, hospitals must ensure the correct and safe application of medical devices and treatments using a variety of tools; these include the education and credentialing of medical staff and competency testing of technical staff. Virtua radiological technologists are licensed by the NJDEP, certified by the ARRT and participate in ongoing quality assurance and education programs. The application of SE #47 must apply to practitioners as well.

In order to accomplish this goal, as a physician user of c-arm mobile fluoroscopes you will be asked to participate in our newly established Physician Fluoroscopy User Competency Review Program. The program will ensure you have timely information on the safe application of fluoroscopy to your patients and the protection of hospital staff present during the procedure. The program includes the following provisions:

1. A brief education packet on safe use of fluoro, dose reduction techniques and the philosophies of ALARA and Image Gently/Image Wisely
2. An attestation form indicating a complete review of the educational packet and adherence to it’s principles and Virtua policies
3. A list of compliant physicians will be maintained on the Virtua Radiology QA Program SharePoint website. Operating Room directors will be given copies of their staff lists to ensure all physicians are accounted for in the program.
4. Reminders for annual reviews will be sent to the OR Directors.

The expectation is that all physician users of fluoroscopic units who wish to operate or utilize operation of the units by a Virtua radiologic technologist will complete the review and attestation. If a physician does not complete the program and attestation use privileges may be suspended until these are completed.

Please direct any questions on the specifics of the program to the Department of Diagnostic Imaging Physics by contacting Michelle Voorhees (x43737, mvoorhees@virtua.org) or Dan Januseski, Dir. (x74436, djanuseski@virtua.org). Thank you for your support of our initiative.
Reduction of Patient and Staff Dose
In Mobile C-Arm Fluoroscopy

The control of radiation dose during fluoroscopic procedures is a critical yet sometimes overlooked part of diagnostic imaging. During particularly difficult invasive procedures, it is easy to lose track of the amount of radiation exposure time. Yet cases have been well documented of acute radiation injury* (FDA, 1994) resulting from as little as 40 minutes of accumulated beam on time; furthermore, chronic low-dose exposure to scatter x-rays by hospital personnel can contribute to increased lifetime risk of cancer in very significant ways.

Virtua ascribes to the principles of ALARA (As Low As Reasonably Achievable) in maintaining radiation exposure to acceptable risk levels. As a physician-operator of fluoroscopic equipment, your understanding of methods to control patient dose will help us achieve ALARA and provide the safest environment for our staff.

DOSE and DOSE RATE

The radiation dose is the total amount of ionizing energy delivered to and absorbed by human tissue. Thresholds exist for acute effects such as skin burns and erythema, cataracts and radiation necrosis. The dose rate is the amount of radiation dose delivered per unit of time and is unique for each x-ray unit dependent upon its characteristics and the settings used to make the image.

Typical dose rates for hospital mobile c-arms are between 10 and 30 mGy per minute. Radiation skin injury has a threshold of about 2000 mGy. Dose rate is not constant. It is affected by the tube settings, such as kVp, filtration and focus size (“MAG” mode). Distance very strongly affects dose rate. If a beam is measured to have a skin dose rate of 20 mGy/min when positioned at 1 meter from the patient’s skin, and the tube is moved closer to, say, 0.5 m (1/2 the distance), the skin dose rate becomes 80 mGy/min due to the inverse-square principal. Now, it will take about 15 minutes to reach the skin injury threshold, an easily achieved scenario in the O.R.

Many modern fluoroscopes also have a feature called “high-dose” mode which can be activated on the foot pedal. This feature allows for extremely high dose rates to penetrate very large patients or very dense tissues. It should only be used to record an image such as a few seconds of a contrast run, and used very sparingly over all. Dose rates in this mode have been measured on our equipment up to 200 mGy/min, which, with direct exposure for just a few minutes, can result in accumulated doses leading to skin injuries.

TO BE AWARE OF:

1. PROXIMITY OF X-RAY TUBE TO THE PATIENT

Point sources of radiation such as in the C-arm follow a very simple and predictable law in calculating their intensity: the Inverse-Square Law. The Inverse-Square Law states that the intensity of an x-ray beam varies as the inverse of the square of the distance from the source to the receptor surface. Thus, for each doubling of the source-to-receptor distance, the beam intensity is ¼ or reduced by 75%. This is a powerful tool for managing doses to a patient’s skin surface.

2. PROXIMITY OF IMAGE INTENSIFIER TO THE PATIENT

If the distance between the patient and the II (Image Intensifier) is shortened, the II acts as a shield and absorbs the forward scatter from the patient, thus reducing exposure to staff standing opposite the x-ray tube.

3. SHIELDING

   - Protective garments – all personnel in attendance in the fluoroscopy room must wear protective lead apparel of at least 0.5 mm thickness or equivalent (NJ law)
When a staff member’s hands need to be in or in close proximity to the central beam, use of leaded gloves or lead-impregnated surgical gloves is required as well.

“Gonadal shielding of not less than 0.5 mm lead equivalent shall be used on a patient during radiographic and fluoroscopic procedures, except for cases in which this would interfere with the diagnostic procedure.” N.J.A.C. 7:28-15.9(3

4. REPORTABLE EVENTS

There are two reporting thresholds for fluoroscopy which all physicians must adhere to. The first is radiation exposure to a patient which results in excess of 15 Gy (1500 rad) to a patient from a single or series of fluoroscopic events. This is defined by JCAHO as a Sentinel Event, and will be handled according to hospital policy. The second reportable event is an internal standard set by Virtua. Any fluoroscopy case which exceeds 5000 mGy of dose is to be reported to the Radiation Safety Office by the physician or technologist. This case will then be investigated by the physicist to determine what risk, if any, of radiation injury may occur. This Reportable Event is not to infer that there was any negligence or error on the part of any staff involved; in fact, in many cases it is an unavoidable consequence resulting from the inherent difficulty of the case. But it provides a quality assurance tool to assess methods and technology for further reducing excessive doses, and alerts the attending and referring physicians to monitor the patient for signs of radiation injury so they can be identified and treated promptly. A report on the risk of injury and dose outcome will be presented to the attending physician along with consultation on what to look for, and the recommendation to discuss that with the referring physician and patient. Through this mechanism, the severity of any potential injury can be reduced.

5. Who may use a c-arm?

Source: Compliance Guidance of Fluoroscopic Quality Control, NJDEP, BXC

“Only a New Jersey licensed physician, podiatrist, or chiropractor, or a New Jersey licensed diagnostic radiologic technologist is permitted to operate any type of medical diagnostic x-ray equipment and position patients for radiological procedures. The activation of the x-ray exposure for fluoroscopic procedures by a licensed diagnostic radiologic technologist is only permitted if a licensed physician is in the room and directing fluoroscopic procedures. "OPERATE" means the use or manipulation of x-ray equipment in any way that leads to or causes the emission of radiation or affects the amount or quality of radiation that is received by a patient. Examples of "operate" include activating or terminating the x-ray exposure, setting or adjusting technical factors, setting the mode of imaging, setting the camera rate, and setting or adjusting the collimator. Tasks associated with turning on the x-ray equipment at the beginning of the day without a patient on the table, resetting the five minute timer, adjusting the imaging monitor, and post exposure data processing are not considered operating x-ray equipment. "POSITION PATIENTS" means the alignment of the x-ray tube, imaging receptor (image intensifier) and the area of the patient intended for exposure to radiation.”

6. Mini vs. Regular C-arm

There are no differences in state regulations between using the mini c-arm or it’s larger counterpart. All personnel must wear lead or stand behind the shield. All rules stated above apply equally, whether a technologist is in the room with physician or not. Please note, if using the mini c-arm, machine movement, patient positioning and all technical parameters must be done solely by the physician.

7. QUESTIONS OR CONCERNS

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I, ________________________________, have read the above information and agree to follow all NJDEP regulations with reference to radiation and radiation safety.

Date: ___________________ Signature: ___________________