



THE NEW YORK STATE RADIOLOGICAL SOCIETY, INC.

A CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY
www.nysrs.org



August 26, 2015

Katherine Ceroalo
Bureau of House Counsel
Regulatory Affairs Unit
New York State Department of Health
Room 2438
ESP Tower Building
Albany, NY 12237

Dear Ms. Ceroalo:

We are writing on behalf of the New York State Radiologic Society (NYSRS) and the Medical Society of the State of New York (MSSNY) to provide comments regarding proposed State regulations affecting the practice of Radiologic Technology (RT) which were published in the New York State Register on July 29, 2015.

The NYSRS and MSSNY have serious patient safety concerns with provisions of the proposed regulations pertaining to the physician supervision standard for RTs performing fluoroscopy and insufflation as well as the level of physician supervision for the operation of conebeam computed tomography (CBCT) by dental assistants. Our specific comments are provided below.

RT Physician Supervision Standard, Fluoroscopy

The proposed regulations change the physician supervision standard for RTs from **personal to direct** for the performance of fluoroscopy to verify the placement of an intravascular line such as a peripherally inserted central catheter (PICC) that was inserted by a licensed practitioner, physician assistant (PA) or nurse practitioner (NP). Personal supervision requires a physician to be physically present in the room where the procedure is being performed while direct supervision does not.

We strongly recommend that the current personal physician supervision standard be retained to ensure that patients are not exposed to increased levels of unsafe radiation. Fluoroscopy can deliver large doses of radiation to patients. It imparts a relatively high radiation dose when compared to other diagnostic imaging procedures.¹ Under the proposed direct supervision standard, a physician may not be readily available if the RT has difficulty operating the

¹ Frederick-Dyer, et al. Online Training on the Safe Use of Fluoroscopy Can Result in a Significant Decrease in Patient Dose. Acad Radiol Vol 20, No 10, October 2013.

equipment or other patient safety issues arise. A PA or NP who inserts a PICC line does not have the adequate training and education to lead a fluoroscopy procedure and protect a patient from harmful levels of radiation.

In addition, X-ray is currently the standard practice for verifying the placement of an intravascular line. It is more accurate and safer for the patient. It provides a clearer image of the tiny tubes used in a PICC line that can be missed by fluoroscopy. X-ray emits less radiation than fluoroscopy and can be used more safely when a procedure runs longer than expected. The NYSRS and MSSNY are concerned that relaxing this supervision standard could encourage fluoroscopy in place of X-ray leading to inferior diagnostics and increased radiation exposure to patients.

Air Insufflation, RTs

The proposed regulations authorize RTs to perform air insufflation as a required component of an imaging procedure under the **direct supervision of a physician**. It is our understanding that the proposed regulation is targeted at procedures involving virtual colonoscopy. However, the proposal is open-ended and authorizes RTs to perform air insufflation as a required component of any imaging procedure.

The process of insufflating air directly into the colon can lead to serious complications including perforations of the colon and life-threatening peritonitis if the incorrect amount of pressure is used. Therefore, the physician supervision standard for insufflating air into the colon by an RT should be personal supervision. The NYSRS and MSSNY recommend the following amendments to the proposed regulations:

Part 89.2 (a) (10) (NYCRR, Title 10) (Deletions in strike-out, additions underlined in bold)
(10) performing manual air insufflation as a required component of an imaging procedure, under direct supervision of a physician such as a virtual colonoscopy procedure or a barium enema procedure under the supervision of a physician as follows:

(i) initial insertion of the tip of the balloon tube under the direct supervision of a physician;
(ii) inflating the balloon at the end of the tube under the direct supervision of a physician; and
(ii) insufflating air into the colon under the personal supervision of a physician.

Cone Beam CT Performed by Dental Assistants

The proposed regulations provide that a **dental assistant is exempt from certification as an RT when operating, under the general supervision of a dentist, conebeam computed tomography** after demonstrating satisfactory completion of a training program approved by NYS DOH or one provided by the equipment manufacturer.

Dental assistants are currently authorized to operate conventional radiographic dental equipment and panoramic radiographic dental equipment under the general supervision of a dentist. Dental assistants do not currently have the authority to operate CBCT.

If authority is granted to dental assistants to operate a CBCT the level of supervision by the dentist should be personal or direct because of the potentially significant doses of radiation that the CBCT emits, particularly since many patients are children. Cone beam CTs produce much

higher radiation doses than panoramic imaging. Compared with conventional radiography, the effective dose of CBCT is several to hundreds times higher.²

The national Image Gently in Dentistry Campaign recommends a six point plan for minimizing radiation exposure to children. This plan includes direction to “Use cone beam CT only when necessary.” The Image Gently website notes that “The scattered radiation dose from CBCT is substantially higher than for panoramic units (about an order of magnitude) due to the significantly larger field of view exposed in CT systems.”
<http://www.radiologyinfo.org/en/info.cfm?pg=dentalconect>

In addition, the Radiological Society of North America and the American College of Radiology recommend that because children are more sensitive to radiation, they should have a conebeam CT scan “only if it is essential for making a diagnosis and should not have repeated CT exams unless absolutely necessary.” <http://www.radiologyinfo.org/en/info.cfm?pg=dentalconect>

Finally, the National Council on Radiation Protection and Measurements (NCRP) is currently in the final stages of completion of a report (*Radiation Protection in Dentistry and Oral and Maxillofacial Imaging*) to be issued early in 2016 which will contain specific recommendations on CBCT. These recommendations will include the need for periodic testing of CBCT by a medical physicist, indications for use, and proper training and ongoing education of clinicians and operators of CBCT equipment. We recommend that this proposed regulation to authorize dental assistants to operate CBCT be withdrawn until the NCRP report is released and studied.

Thank you again for the opportunity to provide written comments on these proposed State regulations. Please contact Shauneen McNally, Government Affairs representative for the NYSRS at 518-465-7330 or shauneenm@lobbywr.com if you have any questions or would like additional information.

Sincerely,



S. Richard Cavoli, M.D.
President, NYSRS



Joseph Maldonado, M.D.
President, M

² Li. Patient radiation dose and protection from cone-beam computed tomography. *Imaging Sci Dent* Vol 43, No 2, June 2103.