X-ray Newsletter

January 2009

Division of Environmental Health ~ Radiation Protection Section

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Image Gently Campaign: *Children are not small adults*

"One size does not fit all" was the statement made when the Image Gently campaign began in 2006. The primary concern and reason for the campaign's initiation is the high dose of radiation to pediatric patients during computed tomography (CT) exams.

The campaign resulted in the formation of the Alliance for Radiation Safety in Pediatric Imaging, comprised of 13 different health care organizations and launched in January 2008. The Alliance's purpose is to promote best practices in pediatric diagnostic imaging.

Donald Frush, MD, chair of the American College of Radiology Pediatric Imaging Commission, with a patient at Duke University Medical Center. Dr. Frush is part of the Image Gently Steering Committee.

Multiple studies done at Duke University and the University of North Carolina at Chapel Hill have documented the increase of CT procedures performed in the United States. In 2006, 60 million CT scans were done with six million of those on pediatrics patients. Computed tomography is not the only concern because As Low as Reasonably Achievable (ALARA) is based on the assumption that any ionizing radiation exposure involves risk.

Exposing children to radiological treatments involves additional issues not found with adult patients. Children are smaller, more radiosensitive and less compliant than adults. The primary problem that makes pediatric imaging more difficult and sometimes requires additional exposures is the child's lack of understanding. Radiographic studies on pediatric patients are often done in the supine position since the patient may be too young to stand or hold a position without assistance. This means the dose could be higher due to shorter source-to-image distance.

Reducing radiation exposure to children requires education. Physicians, medical physicists, technologists, parents and the press all have a role. Information may be found online at: www.imagegently.org.

The following are suggestions and methods to reduce exposure levels.

- Provide oversight of imaging practices among clinicians.
- Order an exam routinely only if the results will have an effect on the treatment plan.
- Select the correct imaging modality
- Tailor exams to the diagnosis (i.e. scoliosis series). The first image should be diagnostic quality. Subsequent images taken only to demonstrate curvature may allow for less optimal images that use a lower dose.
- Reduce the number of views to those actually needed for individual diagnosis.
- Avoid repeat exams.
- Use good geometry.
- Make sure appropriate quality control programs are in place.
- Process films correctly.
- Change imaging techniques based on individual patient size and weight to minimize dose.
- Develop technologists' understanding of the fundamental of computed radiography and digital radiography.
- Work to establish definition and standardization of appropriate CR and DR exposure levels for common procedures based on patient size and age. Since there is no black film to indicate over exposure as in screen film, a careful record of dosage over time will help establish minimum exposure techniques.

What You Need to Know

Beginning Jan. 1, 2009, the Radiology Compliance Branch will begin to issue violations for radiation safety programs that are not updated to reflect radiation safety practices and the radiation safety guide. The branch has been educating registrants through annual newsletters since 2006 to review and update their radiation safety programs. Currently, staff are providing presentations on how to develop and customize these programs in regional Area Health Education Centers. Please visit the AHEC Web site at: www.ncahec.net to pursue these education opportunities. If you need a representative to visit your facility, contact a regional inspector by going online to www.ncradiation.net.

Inspection Focus Transitions

While the core radiation safety principles remain unchanged over time, new technology requires the agency to examine efficiency and effectiveness. Registrants are in a state of transition from film-screen to digital modalities. The RCB had to transition to equipment that can work both for digital and film-screen modalities during the inspection process. With that change completed, staff have begun to transition its inspection protocols to meet the demands of new technology.

The inspection protocols are changing from predominately equipment measurements to performance-based measures. More meaningful measurements with branch equipment means less time in the radiographic rooms during inspections. Inspectors will continue to review basic required paperwork regarding registration, installation and maintenance of X-ray equipment while in the facility. A checklist of the required documents is located online at: www.ncradiation.net. Inspectors will review the facility radiation safety program content, documentation supporting annual review and the program's implementation during the inspection. The primary focus is, and always will be, radiation safety and how it is implemented in the facility.

If you own, possess or use X-ray equipment in North Carolina you are required to:

- Have all equipment registered with this agency.
- Report when equipment has been stored, sold or transferred immediately.
- Notify the Radiation Protection Section if you sell your practice.
- Review your Notice of Registration for accuracy. If any information on the form has changed, including equipment, address, contacts or contact information, notify RPS immediately.
- Provide access to authorized representatives who have the authority to enter any facility at reasonable times to determine compliance. Reasonable hours are the operating hours of the business Monday through Friday.

To facilitate this process and ensure compliance on inspections, the RCB staff encourages you to review and update your radiation safety programs to the current state guidance. There is a guide to assist you in designing and customizing your radiation safety program on the RCB Web site.

Regional inspection staff are available to answer your questions and do presentations in your respective regions. Contact information is available online at: www.ncradiation.net/Xray/regions.htm. If you click on the region of your work, the contact information for the regional inspector will appear.

Tips for a Great Written Safety Program

- Keep it SHORT! Make sure all necessary information is included, but keep it to the point.
- Make sure all allowable personnel monitoring doses are actually written in the program. Each written safety program can cite the regulation book, but the actual allowable limits have to be written out in the program.
- Include the radiation safety officer's duties and make sure they know how to perform these duties.
- Know your retention schedule for equipment and dosimetry. Records should be kept indefinitely for the life of the room and equipment.
- Be sure to EXPLAIN the type of training the operator receives. Do not just name the school or program, but give credentials, if applicable, and explain the content and length of the training.
- Familiarize yourself with ALARA.
  - Remember to keep exposure time to a minimum.
  - Keep an increased distance between the source of radiation and operator.
  - Use adequate shielding.
  - See Reference Guide "ALARA" and "Purpose and Guidelines for Developing a Written Safety Program" on the branch's Web site.

Be sure to include your facility's pregnancy policy. See the Reference Guide, Pregnancy-Employee/Patient at: www.ncradiation.net/x-ray/reference.htm.

Finally, see the Safety Program Guide at: www.ncradiation.net/x-ray/x-ray.htm for additional information.

Image Gently Campaign *(cont. from p. 1)*

While risks involved in projection radiology are low compared to CT, efforts to reduce dosage in both are worthwhile as long as the image quality is maintained.

Medical physicists, radiologists and technologists working as a team can develop the necessary changes to reduce exposure to pediatric patients without sacrificing image quality or level of patient care.

Coming Soon: Image Gently Reference Guide
www.ncradiation.net.

Check out our Web site!
www.ncradiation.net

CeSub: What and How?

North Carolina registrants and service providers are required to report adverse events and complete specific U.S. Food and Drug Administration forms. These reporting requirements are currently captured via a federal electronic reporting system, called CeSub (Center for Devices and Radiological Health electronic Submissions).

CeSub was created as a result of two very successful starter programs named "eLaser" and "Turbo 510(k)." CeSub is a new tool to collect and submit data. This program is improved and is now available for voluntary use by service providers and manufacturers in the radiological health industry.

CeSub is **FREE**! See www.fda.gov/cdrh/cesub/ for more information or to download the free software.

Some of the things that the CeSub will allow registrants and service companies to do include:

(1) Complete and submit information for a variety of radiation safety product reports and annual reports for radiation-emitting products to the Radiological Health Program;

(2) Complete and submit the MedWatch 3500A form for medical equipment adverse event reports; and

(3) Complete and submit the form FDA 2579 for Report of Assembly of a Diagnostic X-Ray System.

MedWatch: What it is and why it is important to you

The FDA has the responsibility of making sure that all regulated, marketed medical products are safe for consumers. This includes X-RAY! MedWatch is used to report safety information and any event that may be harmful for users. This means it distributes safety information and investigates and monitors harmful events that are reported. Some of the areas covered are medical products, including prescription and over-the-counter drugs, medical devices and radiation-emitting devices.

MedWatch distributes product safety alerts, recalls, withdrawals and labeling changes that may affect the well-being of Americans. Through the Web site, www.fda.gov/medwatch/what.htm, you can view reports, safety notifications and label changes from 1996 to present. MedWatch also allows health care workers and consumers to report any problem that may have incurred while prescribing, dispensing or using such associated drugs or devices. This would include any event that would have occurred during the use of radiographic equipment. Sometimes it may be the facility's choice to report an event, and sometimes there is no choice involved.

Voluntary or "Choice" Reporting

Voluntary reporting is accomplished by using the FDA Form 3500. This form can be found on the FDA's Web site. This is used to report spontaneous events that occur during clinical care but not events that occur during clinical trials or studies. The FDA does rely on these voluntary reports in order to keep effective drugs and devices available on the market. This leads to increased patient safety and safety is the number one goal.

Mandatory, "Not a Choice" Reporting

There are occasions in which events are mandated to be reported. This means that there is not a choice. Nursing home facilities and hospitals are mandated to report any suspected medical equipment-related deaths or serious injuries. The FDA and equipment manufacturer must be notified. The FDA 3500 form is to be used; it can be downloaded from the FDA's Web site, which is listed below. This reporting can be done online, by phone or by the MedWatch 3500 form. To report, go to www.fda.gov/medwatch/feedback.htm.

Contacting MedWatch

- **Mailing address**:
  MedWatch –
  Office Of The Commissioner
  Office of Scientific and Medical Programs
  5600 Fishers Lane, Room 12B05
  Rockville, MD 20857
- **For answers to questions about specific products:**
  - FDA Index – www.fda.gov/opacom/hpchoice.html
  - Drug Information Pathfinder – www.fda.gov/cder/Offices/DDI/pathfinder.htm
- Call 1-888-INFO-FDA (1-888-463-6332) to speak to an FDA representative or Medical Devices at 1-800-638-2041.

Facts About X-ray

The use of X-ray machines has been regulated by the RPS since 1964, when the initial regulations were adopted by the General Assembly. All users of X-ray producing equipment are regulated, except federal agencies and Indian health agencies.

Two primary groups make up X-ray users: healing arts and non-healing arts applications. The category of users in the healing arts range from the use of X-ray imaging in hospitals, clinics, physicians, chiropractors, dentistry and veterinary practices.

The use of X-ray in non-healing arts ranges from learning labs at universities and industrial radiography to law enforcement applications for bomb detection or finger printing and irradiation for communicable disease control.

Presently there are 7,220 X-ray registrants with a total of 22,504 tubes. These registrants are inspected on a two-, three- or four-year frequency, which was determined by the state's fee program. All registrants are inspected according to the *North Carolina Regulations for Protection Against Radiation* and any applicable federal requirements.

Frequently Asked Questions

Q: I have just recently changed from film-screen to digital radiography in my dental practice. I believe the exposure is much less, and I do not need to use lead aprons or monitor dose. Is this accurate?
A: No. It is important to remember that radiation is elective and cumulative. No matter how low the dose, the public as well as the employee have a right to be protected. The dose or amount of radiation acquired during an exam is forever!

Q: Dental and podiatry machines do not give off scatter or even a measurable amount of radiation, so why should we be concerned about monitoring or dose?
A: Once again, it is cumulative, whether it is a small dose or a large dose. According to 15A NCAC 11 .1614, the registrant has to demonstrate that the individual is not receiving more than 10 percent of his annual dose. How this is being accomplished in your facility is one of the questions asked during an inspection.

Q: The Web site for Radiation Protection is difficult to use, and it does not really pertain to me and my practice.
A: The Web site has just recently been updated with input from registrants and service providers. There are new reference guides on safety programs, exit signs, registration requirements, mobile equipment, plan reviews, hand-held dental units, signs and postings, and smoke detectors. There is also a campaign for CT users that addresses imaging techniques and factors to reduce dose. See www.ncradiation.net?x-ray/reference.htm.

Q: What is a radiation survey versus a shielding design?
A: Both the shielding design as well as the survey are performed by a service provider registered with the State of North Carolina. The shielding design is done and acknowledged by the state prior to installation of the equipment, whereas the survey is done within 30 days of initial equipment operation. These two documents should be kept indefinitely for the life of the equipment or facility. The shielding design documents what it takes for your facility to be safe in accordance with the rules. This includes a drawing of the room with specifications as to what should be incorporated into the walls to prohibit unnecessary exposure. The survey proves that the areas within and around the room are safe. The survey includes a drawing of the room with scatter measurements demonstrating the shielding integrity.

Q: What is my registration number?
A: This is the number established when you register your facility. It should be included on any correspondence to the office, and it is always found on your Notice of Registration or letters from the RCB to you. If you are a new facility, this number will be created once you have provided your application to register your equipment.

Q: Can I fax in my application of registration or updated NOR?
A: Yes, you can, but remember to sign and date the forms.

Q: How long does it take to receive an acknowledgment letter?
A: The RCB staff evaluates shielding designs daily, and they are evaluated in the order in which they are received. Please plan ahead, so staff can review them and send the acknowledgment letters in a timely fashion. You must have the acknowledgment letter prior to installing your equipment.

Q: The Written Radiation Safety Program is long and wordy. I cannot be sure that my employees are actually reading it before they sign it. How can I ensure that they know the facility's policies and procedures?
A: First, as of Jan. 1, 2009, the model guide for the written safety program will no longer be accepted. Each facility is responsible for writing a written radiation safety program commensurate to the scope of the practice. In other words, make it short and to the point. Do not add a lot of unnecessary jargon to it. Secondly, hold your employees responsible by testing them after the fact (either verbally or in writing), and document their results. This test would not only prove they read it, but they understood it. When you are inspected and questions are asked by the inspector, there is documentation that each operator read it and knew the essential information.

Q: Do I have to provide (wear) dosimetry?
A: In one year, adults are likely to receive a dose in excess of ten percent of the limit (500 milliRoentgen) and therefore must be monitored. A second principle, ALARA, must also be demonstrated. It is the registrants' responsibility to demonstrate compliance with these requirements. At the time of inspection, monitoring records and documentation supporting your decisions regarding monitoring will be evaluated.

Q: I am a new owner of a practice that is either new or pre-existing. What do I have to do?
A: In either a new facility or transfer of ownership, the owner assumes responsibility and must register their facility and all X-ray equipment. Registration forms can be downloaded from the branch's Web site. New registrants are required to maintain documents specific to those described by the regulations and be available for state inspections. If you have questions, refer to the checklist for inspections online or contact the RCB office.

Q: I am about to transition to DR or CR, do I have to do a shielding design (also known as a plan review) as well as a radiation survey?
A: With a new modality, a registered service provider should be contacted to determine if the specifications for the existing shielding is sufficient and if a new shielding design is needed. Radiation surveys are required for all installations. They are also required if the output is increased, work load increases or occupancy of the adjacent area has changed. This also includes when any structural modifications have been made. A list of registered service providers can be found on the RCB Web site.

Q: Who can install, service or sell equipment to my facility?
A: Individuals registered with RPS to perform those services in this state are the only individuals that can install, service or sell equipment in North Carolina. The RCB Web site contains a list of all North Carolina registered service providers.

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