



North Carolina Department of Health & Human Services  
Division of Health Service Regulation • Radiation Protection Section

## The 20th anniversary of the passage of the 1992 Mammography Quality Standards Act

The **Mammography Quality Standards Act (MQSA)** was enacted by the United States Congress to regulate the quality of care in mammography. The act was officially effective in 1994, and was extended in 2004 to continue through 2007. The U.S. Food and Drug Administration (FDA) began inspections of mammography facilities to ensure compliance in 1995. In 1997, more comprehensive regulation was added to become effective in 1999. The Mammography Quality Standards Act requires mammography facilities across the nation to meet uniform quality standards, to assure high-quality mammography for early breast cancer detection, which leads to early treatment, a range of treatment options leading to an increased chance of survival. Under the law, all mammography facilities must:



- 1) be accredited by an FDA-approved accreditation body,
- 2) be certified by the FDA or a certifying State, as meeting the standards,

- 3) undergo an annual MQSA inspection, and
- 4) prominently display the certificate issued by the agency.

MQSA ended the use of modified X-ray devices for mammography by mandating dedicated equipment. It has established national quality standards and certification for physicians, technologists, and physicists. Compliance with the rule means conducting and maintaining documentation of daily, weekly, quarterly, semiannual, and annual quality control tests. Sites must apply for accreditation and undergo annual inspections

Recognition that screening could have a powerful impact on early breast cancer detection emerged in the mid 1980s. This recognition was first addressed in 1987, when the American College of

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## 1992 Mammography Quality Standards Act, continued from page 1

Radiology began its voluntary accreditation program. This action occurred at a time when mammography screening was becoming widely adopted, yet image quality, equipment, and radiation dose for the procedure varied considerably. Despite the ACR's efforts, by 1992, only about 7,200 facilities out of an estimated 11,000 had applied for accreditation, and only approximately 4,600 were accredited. During this time, states began establishing laws governing mammography quality. The resulting patchwork of policies and continuing quality problems culminated in congressional action, with

the passage of the MQSA in 1992, and mandatory in October 1994.

MQSA is intended to maintain high quality mammography in the United States and its territories. Congress found it necessary to bring all participants concerned with mammography into accord, to assure quality breast imaging to all women. Sites that could, complied with the new rules and others who couldn't ceased mammography services. This left the field of breast imaging to those who were committed to providing quality services.

Today the outcome of MQSA is that nearly 70% of facilities now pass inspection without any violations, and fewer than 2% of violations issued are for the most serious level. Through MQSA, the importance of mammography increased in visibility, as well as, importance among hospital executives. MQSA gave mammography screening respect, providing it meant your facility met the required standards and achieved the necessary levels of quality. MQSA allowed mammography facilities to incorporate federal regulations and to implement quality measures that are reproducible across institutions. ●

## MQSA National Statistics

In this section of the MQSA Scorecard, we present the most commonly requested national statistics regarding the MQSA program. These statistics are updated on the first of each month.

<b>Certified facilities, as of October 1, 2012</b>	<b>8,654</b>
<b>Certification statistics, as of November 1, 2012</b>	
Total certified facilities / Total accredited units	8,647 / 12,474
Certified facilities with FFDM2 units / Accredited FFDM units	7,526 / 11,025
<b>FY 2013 inspection statistics, as of November 1, 2012</b>	
Facilities inspected	535
Total units at inspected facilities	735
Percent of inspections where the highest noncompliance was a:	
Level 1 violation	0.9%
Level 2 violation	13.6%
Level 3 violation	0.7%
Percent of inspections with no violation	84.7%
Total annual mammography procedures reported, as of November 1, 2012	38,884,700

## ARRT Documentation of Initial 25 Supervised Exams

Documenting initial training for technologists looks easy, but depending on the training facility can leave both the technologist and inspector extremely frustrated.

The Policy Guidance Help System states: Under 21 C.F.R. 900.12(a) (2): In order to independently perform mammographic examinations, one must first be a qualified radiologic technologist.

1. Be State licensed<sup>1</sup> to perform general radiographic procedures, or have a general Certification from an FDA-approved body<sup>2</sup> to perform radiologic examinations.
2. Have prior to April 28, 1999, qualified as a radiologic technologist under the interim regulations<sup>3</sup>; OR completed 40 contact hours of specific training in mammography in the topics specified in the regulations, including performance of a minimum of 25 examinations under direct supervision<sup>4</sup>.

MQSA qualifying date occurs at the completion of the 25th supervised exam “Mammography Clinical Experience Requirements” document released 7/1/2009 and effective 7/1/2011 the ARRT shifted from listing the 25 supervised exams to an attestation format that states “I have met the initial MQSA qualifications for mammography.” Most formal mammography programs credit the technologist with 28 to 32 hours of training. Expecting the technologist to fulfill the final 12.5 hours with 25 supervised exams; the inspector can only use this information, if the date initiated and completed are included, as well as time spent performing each exam, 12.5 hours would equal approximately 30 minutes per patient. Also, the verbiage of the 2009 ARRT attestation does not clarify that it was signed and verified on the date the 25th exam was actually completed. ARRT has issued a revised clinical experience document 7/1/2012 effective 7/1/2014 adding to the attestation statement: “Initial MQSA (Mammography Quality Standards Act) requirements include,

among other provisions, completion of 25 supervised mammography examinations. Documentation of completion is required by MQSA. ARRT requests only signature verification that you have completed these requirements.” Some mammography course instructors encourage students to copy the “Mammographic Exam Documentation” page from the application before the 75 additional exams are documented for use as documentation of the 25 supervised exams. This will suffice but the “time of day” column is more useful to the inspector if the time spent on each exam is included.

The way you document your initial training is what an inspector will examine to assign a qualifying date. Correct documentation will make the process less complicated and may save the technologist and the facility from a non-compliance citation (Level II). ●

**You may review the 2009 document effective 7/1/2011 at the following link:**

**<https://www.arrt.org/pdfs/Disciplines/Clinical-Experience/MAM-Clinical-Experience-2009.pdf>**

**You may review the 2012 document effective 7/1/2014 at the following link:**

**<https://www.arrt.org/pdfs/Disciplines/Clinical-Experience/MAM-Clinical-Experience.pdf>**

## Hologic Updates Infection Control Recommendations

Hologic users are accustomed to selecting an approved cleaning solution from a list of tested solutions found on technical bulletin TB00140. In March 2012, Hologic issued technical bulletin TB00555. This bulletin shifted focus from name brand solutions to maximum ingredient concentration levels found in all solutions.

A review of MQSA regulations regarding infection control stresses the importance of manufacturer recommendations in choosing a high level disinfectant that will not degrade contact surfaces or void the unit warranty. Referenced from the Policy Guidance Help System: Citation:900.12(e)(I3) (i),(ii),(iii). Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on

infection control, until such recommendations become available.

To "specify the methods for documenting facility compliance" Hologic users will need to evaluate the concentration of ingredients in their chosen high-level disinfectants using TB00555. Include in your written policy all supporting documentation as follows:

- Detailed written procedures describing actions taken in the event of a high level occurrence (what is considered high level, cleaning instructions, solution contact time, how the incident is documented)
- Your chosen solution label (showing viruses/bacteria affected with contact time and method of use)
- TB00555
- Hologic cleaning instructions (if available, dependent upon the age of your unit)
- A sample of your method of incident documentation (log or chart)
- MSDS for your chosen solution

Though these documents may not be specifically required by the regulations, note that all clearly support that you "Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility." Be certain that there are no discrepancies across your supporting documents. For

example, your chosen solution names only a few pathogens considered blood and body fluid contaminants and is therefore not a true high level disinfectant. Another example would be a stated solution contact duration for efficacy in your written policy shorter than contact duration stated on the solution label.

Please be aware that Hologic advises in TB00555 that facilities discard copies of TB00140. The presence of both copies in your infection control policy would add unwanted conflict to your written policy. For additional information on infection control, visit the Policy Guidance Help system at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm> ●

## Clinical Laboratory Improvement Amendments (CLIA)

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed in the U.S., through the Clinical Laboratory Improvement Amendments (CLIA). CLIA covers approximately 225,000 laboratories, including those that perform Pap Smears, HIV testing, and Mammography. The goal of the CLIA program is to ensure quality laboratory testing. All clinical laboratories must be certified to receive Medicare or Medicaid payments. Mammography centers are handled differently, where they must apply for and receive certification from the Food and Drug Administration (FDA), which is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic). The FDA provides CMS with a listing of all providers that have been issued certificates to perform mammography services and CMS notifies agencies accordingly.

Most states have implemented their own CLIA regulations, which may be more stringent than federal requirements. For more information concerning CLIA requirements contact:

North Carolina Department of Health and Human Services,  
Division of Health Service Regulation, CLIA Certification  
2713 Mail Service Center  
Raleigh, NC 27699-2713  
Phone (919) 855-4620  
Fax: (919) 733-0176

**CMS.gov**

Centers for Medicare & Medicaid Services

## FDA Safety Alert

The FDA has issued a safety alert to dental and veterinary care professionals concerning the illegal sale of hand-held dental X-ray units that have not been reviewed by the FDA.

The FDA is aware of hand-held dental X-ray units being sold online by manufacturers outside the U.S. and directly shipped to customers in the U.S. These devices may not be safe or effective and could potentially expose the user and the patient to unnecessary and potentially harmful X-rays.

Before utilizing any hand-held X-ray unit an operator should:

1. Verify that your device bears certification, warning and ID labels as described in the FDA Safety Communication.
2. Ask your vendor whether the device has been reviewed and cleared by the FDA.
3. Access the FDA Medical Device Approvals and Clearances searchable database to verify that the X-ray unit you are using has been reviewed by the FDA.
4. If you become aware of a device that you think is hazardous or does not meet FDA's radiation safety or premarket clearance requirements, contact NC Radiation Protection at 919-571-4141 or [jon.granger@dhhs.nc.gov](mailto:jon.granger@dhhs.nc.gov).



**U.S. Food and Drug Administration**

Protecting and Promoting *Your* Health

**The FDA alert can be found at the following link:**  
<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/AlertsandNotices/ucm291214.htm>

**NC Radiation Protection information on the use of hand-held X-ray units can be found here:**  
<http://www.ncradiation.net/Xray/documents/handhelddentgud.pdf>

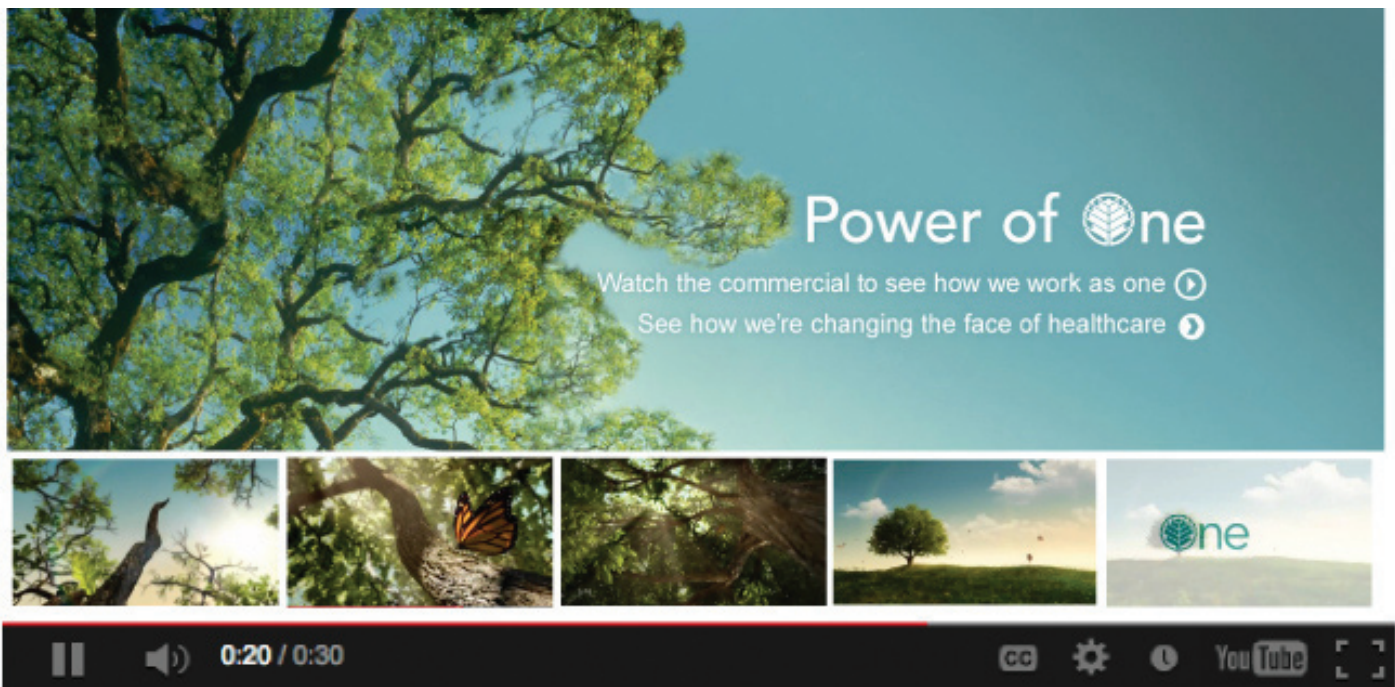
## In the Pink

Pink all over! Facilities are going beyond. Facilities are taking their role in Breast Cancer health personally and coming up with unique and innovative ways to keep their patients coming back for more. Pink all over is an effort to salute those facilities.

CMC Northeast Breast Imaging Center has placed journals in all mammography dressing rooms and invited patients to share their feelings and thoughts, good and bad. Most entries were to thank the staff for their great service and compassionate hearts. Some entries were to thank God, others to ask him why all this is happening to them or how will they get through it? Their journal pages were full of fear, hurt, anger and sadness, but also joy and peace. Journaling gave these patient's permission to voice their feelings without repercussion.

As I spent some time reading page after page, sometimes I would laugh sometimes cry. Reading journal entries was a wonderful way to understand the inner most thoughts of those "survivors" battling with breast cancer who have found a unique to express their feelings. I left feeling uplifted, hopeful and encouraged.

Research has shown that an advantage to journaling is the experience of a greater sense of emotional well-being and to help people feel better physically. Recording their emotions during tough times has been known to ease the stress of day-to-day living, helps to promote personal goals and provides self-encouragement. Thanks to CMC Northeast Breast Imaging Center for sharing their unique approach in helping their patients in the battle against breast cancer. ●



## Council on Licensure, Enforcement and Regulation

Our mission is to be a resource on issues regarding Radiation Protection, a regulatory body whose purpose is to guide our facilities into regulatory compliance. In a Division effort to improve our services we took a course administered by the Council on Licensure, Enforcement and Regulation which is a National Certified Investigator/Inspector Training Program. Local, state and federal government agencies involved in regulations typically

take this to become more effective in providing services such as licensing, registration, and regulatory compliance and enforcement activities. CLEAR brings agencies together to encourage and promote sharing of best practices and encouraging distribution of relevant information for the benefit of public protection. The course included three-days of hands on training on investigation and inspection techniques and procedures. At the end of this three-

day course, we were required to take and pass a certification test with 70% proficiency, which all the employees from RPS did. So we have started the New Year with renewed vigor, renewed compassion, and renewed awareness of the regulatory process and the role we all can play in the area of Radiation Protection. CLEAR's mission is to support us in our mission, and our mission is to support you in yours. ●

## What's Next?

Personnel from the N.C. Radiation Protection Section of DHHS's Division of Health Service Regulation participate with radiation control personnel from 45 other states, in collaboration with the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), and the Conference of Radiation Control Program Directors (CRCPD) in a federal-state partnership to characterize the radiation doses patients receive and to document the state of the practice of diagnostic radiology. CDRH staff compiles, analyzes and publishes survey results on population exposure, radiographic and fluoroscopic technique factors, diagnostic image quality, and film processing quality.

This is called the NEXT surveys, Nationwide Evaluation of X-ray Trends (NEXT). Each year the survey pro-

gram selects a particular radiological modality for study and captures radiation exposure data from a nationally representative sample of U.S. clinical facilities.

"NEXT information gives RPS the information we need to evaluate performance of the practices in North Carolina compared with the same types of practices across the nation," said Jenny Rollins, Radiation Compliance Branch manager. "It is from this data that we make decisions on how to use our education and inspection processes to improve performance in North Carolina."

Survey results also benefit providers by setting a benchmark from which to evaluate how well their performance stacks up against their peers in North

Carolina as well as those in other states.

"NEXT gives us the standard at which we are currently operating, and allows us to see where we should be in terms of dose and image quality," Rollins said.

The surveys capture data on the practice of diagnostic radiology – including radiation exposures, film processing and darkroom environment, X-ray film image quality and information about the facility's general safe practices. Digital Imaging Modality has been added for evaluation and given us great information on the dose reduction with DR.

NEXT surveys continue to provide the answers to question for the FDA and the state surveyors regarding protection the general public from unnecessary exposure to radiation. ●



## Diagnostic Reference Levels (DRL'S)

Diagnostic Reference Level (DRL) is a dose metric to an average size patient or a phantom. Entrance Skin Air Kerma (ESAK) in radiography, Entrance Air Kerma Rate in fluoroscopy, and CT Dose Index (CTDIvol) in CT can be used as parameters in a quality assurance program to identify possible situations where certain protocols, equipment, or procedures may be producing unnecessary radiation doses to patients.

The objective of a diagnostic reference level (DRL) is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. Diagnostic reference levels are determined based upon data collected from nationwide studies such as the Nationwide Evaluation of X-ray Trends (NEXT) Program and are typically set at the seventy-fifth percentile of the study data set. Facilities should perform dose metric comparisons to DRL's to help to identify outliers.

This practice is a useful tool in identifying imaging protocols and practices that may be delivering usually high radiation doses to patients. If a DRL is consistently exceeded, a review of procedures, protocols, and equipment should be performed. If possible, dose reduction measures should then be taken. Satisfying a DRL for a particular exam or protocol does not imply that the protocol or procedure is fully optimized. If an exam or protocol is identified that consistently exceeds the DRL, justification must be provided. Facility staff should consult with a qualified medical physicist regarding the measurement of patient doses for the purpose of comparison of these doses to the DRL.

The qualified medical physicist should make measurements so that the facility can determine the patient entrance dose from the technique factors which they routinely use for each patient exam. Patient entrance doses should be determined for all X-ray units used for specific projections, as doses can vary significantly among different imaging units. Additionally, DRL's should be reviewed with a medical physicist when selecting CT protocol parameters. The Achievable Dose Level (ADL) is another dose metric used and is set at the median dose of the Nationwide Evaluation of X-ray Trends (NEXT) survey data or other survey data on which DRL's are based. The achievable dose level indicates a radiation dose which is readily attainable by 50 percent of the facilities. Please visit the N.C. Radiation Protection website for more information. ●



# Division of Health Service Regulation includes other Regulatory Agencies that may be Impacted when Submitting a Shielding Plan

**Construction Section:** is responsible for performing, reviewing, and approving plans reviews for health care and jail construction projects in the State of North Carolina X-ray equipment that is intended for installation in licensed health care facilities must have a plan review performed by the Construction Section of Division of Health Service Regulation and is required to submit to bi-annual inspections by this same section. These inspections are for compliance with physical plant rules used in construction and renovation projects, not an inspection of X-ray equipment. Facilities that fall under these requirements are: hospitals, hospital based outpatient clinics, ambulatory surgical centers, nursing, adult and family care homes, mental health hospitals, state owned mental health and 24-hour residential mental health facilities, intermediate care facilities for individuals with intellectual disabilities (ICFIID), women's health care and child care centers, hospices, and jails.

For facilities that are subject to Construction Section approval, the Radiation Safety Section will withhold issuing the registration permit for the radiation machine until:

1. The Construction Section has approved the project for that machine and service and
2. The Radiation Safety Section has reviewed and approved radiation shielding plans for the room in which the radiation machine will be used.

**Certificate of Need Section:** is tasked with the control and limit of unnecessary increases in health care costs, by restricting unnecessary health services and facilities based on geographic, demographic and economic considerations.

Some radiation equipment and radiological services are also subject to Certificate of Need (CON) approval.

- cardiac catheterization equipment
- Gamma Knives®
- linear accelerators and simulators
- lithotripters
- Positron Emission Tomography (PET) Scanners
- Any radiographic equipment where the aggregate cost or value of the equipment exceeds \$750,000. *See definition of "major medical equipment," NCGS 131E .176(14o)*
- All diagnostic X-ray centers where the total cost or fair market value of all of the medical diagnostic equipment used by the facility and the costs associated with the equipment exceed \$500,000. *See definition of "diagnostic center," NCGS 131E .176(7a).*

For facilities that are subject to Certificate of Need approval, the Radiation Safety Section will withhold issuing the registration permit for the radiation machine until:

1. The CON section has approved a CON for that machine and service and
2. The Radiation Safety Section has reviewed and approved radiation shielding plans for the room in which the radiation machine will be used.

Inquiries concerning the Construction Section should be submitted to:  
DHSR /Construction Section  
Physical Address:  
1800 Umstead Drive,  
Raleigh, NC 27603

Mailing Address:  
2705 Mail Service Center,  
Raleigh, NC 27699-2705

Phone: 919-855-3893

Inquiries concerning the Certificate of Need Section should be submitted to:  
DHSR /Certificate of Need Section  
Physical Address:  
809 Ruggles Drive,  
Raleigh, NC 27603

Mailing Address:  
2704 Mail Service Center,  
Raleigh, NC 27699-2704  
Phone: 919-855-3873 ●



North Carolina Department of Health and Human Services  
 Division of Health Service Regulation  
 Radiation Protection Section  
 1645 Mail Service Center • Raleigh, North Carolina 27699 -1645  
<http://www.ncradiation.net>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor  
 Albert A. Delia, Acting Secretary

W. Lee Cox, III, Chief  
 Phone: 919571-4141 • Fax: 919-571-4148

## Radiation Safety Month

To aid North Carolina citizens and healthcare providers, the Radiation Protection Section (RPS) pursued through the Department of Health and Human Services a proclamation signed by Governor Beverly Perdue to designate November as Radiation Safety Month. The proclamation was granted and presented to RPS. Radiation safety is a collaborative effort that involves the citizens receiving services, the healthcare providers, imaging professionals and radiation workers who provide the service, and RPS-sponsored initiatives to educate the public and promote instruction and guidance.

The authority to regulate ionizing radiation in X-ray, mammography and radioactive materials facilities and to regulate non-ionizing radiation in tanning facilities resides within RPS. In addition to the regulatory responsibilities, RPS also has a radon program whose sole mission is to educate the public regarding the dangers of radon gas. RPS also conducts environmental radiation monitoring around various locations throughout the state including areas in the vicinity of four nuclear power facilities. North Carolina has more than 7,500 X-ray facilities, 235 mammography facilities, 1,800 radioactive material facilities and 1,400 tanning facilities.

Two of the core missions of the Radiation Protection Section to the citizens of North Carolina are to:

- Reduce radiation exposure to the citizens and occupational workers of North Carolina; reduce radiation contamination to the environment and to protect all from radiation hazards by ensuring the existence of a preeminent radiation safety culture.
- Ensure all licensees and registrants have equal opportunity to comply with applicable regulations through education and guidance.

Success in this mission is dependent upon the assistance of the regulated community and the individual citizens of our state becoming aware of and taking an active role in the radiation safety. RPS constantly seeks opportunities to

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## **Radiation Safety Month continued from page 11**

improve awareness of radiation safety and to reduce radiation exposure to the citizens and occupational workers in our state. Materials such as the dose card and pregnancy posters were developed with the goal that citizens and healthcare providers would work together to improve the health of individuals by learning and sharing information about exposure to radiation. The Radiation Safety Culture Policy Statement and pamphlet were developed to emphasize radiation safety over competing goals to ensure protection of people and the environment.

RPS encourages healthcare providers to promote the use of dose tracking cards. Citizens should keep a record of lifetime doses and the facilities where the X-rays were taken. This may assist the provider in acquiring records of studies that could help in diagnosis or prevent unnecessary repeated exposures.

RPS encourages healthcare providers to post “Inform a Tech” and “Inform a Doctor” pregnancy posters in X-ray rooms. The posters are intended to raise awareness of citizens who may be pregnant of the importance of communicating that information to staff at the facility before having X-rays taken. The posters are free and available in English and Spanish and may be downloaded for printing. They may be found on our website at: **[www.ncradiation.net/Xray/postings.htm](http://www.ncradiation.net/Xray/postings.htm)** .

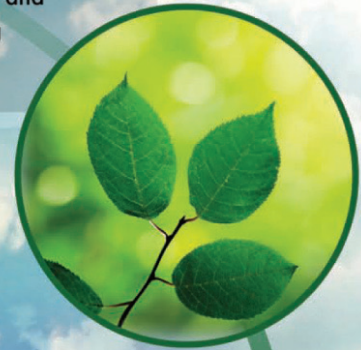
RPS endorses and is committed to the development of a robust radiation safety culture throughout the state. All RPS-regulated facilities are encouraged to promote a culture of radiation safety through review of their radiation safety programs and to ensure all occupational staff have been trained and are aware of radiation safety practices. It is imperative that these entities view safety culture as the core values and behaviors rooted in a collective commitment by leaders and individuals to emphasize safety over competing goals. During radiation safety month we encourage you to designate a day to review and update your procedures if you have not already done so this year. The Safety Culture Policy Statement Pamphlet is attached in the email.

During “Radiation Safety Month” RPS salutes all professionals working throughout North Carolina in the field of radiation to minimize the hazards of radiation exposure. Their efforts resulting in quality care to our citizens is greatly appreciated.

Lastly, please use this proclamation to bring awareness to the citizens and occupational workers of efforts to provide safety practices and to encourage a safety culture throughout the state. For more information visit the following links: Radiation Protection at [www.ncradiation.net](http://www.ncradiation.net). or to learn about radon [www.ncradon.org](http://www.ncradon.org) ●

# North Carolina Radiation Protection Section

"...the core values and behaviors resulting from a collective commitment...  
... to emphasize safety over competing goals to ensure protection of people and the environment."



**SAFETY FIRST**



## Safety Culture Traits

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communication	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be additional traits not included here that are also important in a positive safety culture. These traits were not developed for inspection purposes. North Carolina Department of Health & Human Services, Division of Health Service Regulation, Radiation Protection Section. NC DHEC is an equal opportunity provider and employer. 3/2013



[www.ncradiation.net](http://www.ncradiation.net)

# State of North Carolina



BEVERLY EAVES PERDUE  
GOVERNOR

## RADIATION SAFETY MONTH

2012

BY THE GOVERNOR OF THE STATE OF NORTH CAROLINA

### A PROCLAMATION

WHEREAS, on November 8, 1895, Wilhelm Conrad Röntgen discovered X-rays by producing and detecting electromagnetic radiation in a wavelength range also known as Röntgen rays, an achievement that earned him the first Nobel Prize in physics in 1901; and

WHEREAS, while radiation continues to be a useful and necessary part of our modern world, radiation exposure can be harmful to people; and

WHEREAS, annual effective radiation dose from medical imaging has doubled in the past fifteen years; and

WHEREAS, radiation protection professionals work throughout North Carolina government, industry, medical, dental, educational, research, law enforcement and emergency management communities to bring the benefits of radiation to the people of our state while minimizing the hazards of radiation exposure; and

WHEREAS, children are more sensitive to radiation, the Image Gently Campaign provides optimal scanning for children only when there is a clear medical benefit and to avoid unnecessary scans; and

WHEREAS, exposure to radiation can be reduced through alternative technology such as ultrasound and magnetic resonance imaging, doctors and radiologists can work as a team to select the best imaging exam options for their patients; and

WHEREAS, the State of North Carolina joins the Image Gently Campaign and other interested agencies and organizations to promote awareness of radiation safety and the opportunities to reduce radiation dose, and in encouraging citizens to test and mitigate their homes for radon levels, as well as visit the North Carolina Radiation Protection website [www.ncradiation.net](http://www.ncradiation.net);

NOW, THEREFORE, I, BEVERLY EAVES PERDUE, Governor of the State of North Carolina do hereby proclaim November 2012, as "RADIATION SAFETY MONTH" in North Carolina and commend its observance to all citizens.



*Beverly Eaves Perdue*

BEVERLY EAVES PERDUE

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of the State of North Carolina at the Capitol in Raleigh this eighth day of October in the year of our Lord two thousand and twelve, and of the Independence of the United States of America the two hundred and thirty-seventh.



## Q and A

**Question: Can X-rays be used to make exposures of individuals for training or non-healing arts purposes?**

The answer is in 15A NCAC11 .0603(a) (G) Deliberate exposure of an individual for training demonstration or other non-healing arts purposes is prohibited.

**Question: Who can order X-rays?**

The answer is in 15A NCAC11 .0603(a) (G) X-Ray exposures must be authorized by a licensed practitioner. The N.C. Medical Board has additional requirements requiring the licensed practitioner to be licensed in North Carolina and the NCMB defines the scope of practice for a licensed practitioner. Scope of practice questions should be directed to the appropriate regulating licensing boards such as medical, chiropractic, podiatry, dental, and veterinary.

### 15A NCAC11 General Requirements

(a) Administrative controls (1) The registrant shall be responsible for directing the operation of the X ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the X ray machine(s): Individuals shall not be exposed to the useful beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes

**Further Guidance on Physician orders can be found in our reference guide <http://www.ncradiation.net/Xray/documents/orderxrays.pdf>**

### Authorized Exposures

Physician's orders—the physician's instructions for the care of an individual patient should:

1. Provide accurate detailed information regarding patient history;
2. Specify what procedures/test is required, which may include a written description of the method to be used i.e., standing, flat or mention a specific exam protocol;
3. State any special circumstances and/or limitations; and
4. Document all of the above in writing, dated and signed by the physician.

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**Q and A, continued from page 14**

The physician should be available for consultation, assistance and direction upon the delivery of prescribed X-ray services or in the advent of a medical emergency. According to state regulations regarding the administration of radiation: it is not within the scope of practice for a nurse to independently insert or write in a dosage, time, frequency or route on a prescription or in a medical order blank space. These are components of prescribing and must be determined by the prescriber, physician of record, or his designated stand-in physician. Additionally, it is not within the scope of practice for a nurse to fill in a blank prescription pre-signed by a prescriber with regard to X-ray exams. In the Rules, concerning the administration of radiation, a registered nurse or licensed practical nurse is not authorized to render medical diagnosis or to prescribe a medical plan of care.

The physician understanding the personal and medical history of his or her patient, after the performance of appropriate physical examination and the recording of physical findings, may establish procedures for providing care by his personnel. This can only be done under the supervision of a physician who is directly supervising or overseeing the delivery of medical or health care to his patients.

The Radiology Compliance Branch does not restrict the physician from delegating administrative, technical or clinical tasks that do not involve the exercise of medical judgment by a physician. These clinical or technical tasks would involve specially trained individuals instructed and directed by a licensed physician who accepts responsibility for the acts of such allied health personnel. ●

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## Subscribe to Newsletters and other Resources available online.

All your resources are available on our website <http://www.ncradiation.net/Xray/xray.htm>. From the website you can download or print regulations, caution signs, Notice to Employees. The Notice to Employees and caution signs are provided in English and Spanish. Only the English version is required but based on requests from registrants a Spanish version has been added. Additionally, we got many requests for Pregnancy posters from registrants. We designed one for your use and it can be printed or downloaded from the website as well.

All information regarding inspections is now available at [www.ncradiation.net/Xray/inspections.htm](http://www.ncradiation.net/Xray/inspections.htm)

We have answers in the facility reference guides. You will find your inspection checklist to prepare you for your inspection and guides to develop your radiation safety program with an assessment tool to help you assess your progress. This is the same assessment tool the inspectors use for evaluation. Most recently we recorded live presentations of one of our inspectors doing the complete presentation on how to develop your radiation safety program. You can listen to this that should address all your questions relevant to radiation safety programs.

If you want to stay in touch and know when there are any changes and to receive our newsletters you need to

sign up for the online newsletters and notice. The Branch sends out updates, notices and newsletters through electronic means. If you have missed previous newsletters, no worry they are archived at [www.ncradiation.net/Xray/newslets.htm](http://www.ncradiation.net/Xray/newslets.htm)

To receive future newsletters and notices as they come out please subscribe to our listserve for X-ray at <http://lists.ncmail.net/mailman/listinfo/xraynews> and for mammography at <http://lists.ncmail.net/mailman/listinfo/mammographynews>. These links are especially for our registrants and for anyone that wants to stay up to date with news at Radiation Protection. ●

# New Approach to the Evaluation of Intraoral Equipment

The North Carolina Department of Health and Human Services (DHHS), Division of Health Regulation, Radiation Protection Section is taking a new approach to evaluating image quality and radiation dose for dental intraoral X-ray imaging systems.

In January, 2012 DHHS contracted with an independent firm, DIQUAD, LLC, to evaluate intraoral X-ray equipment via mail. This program utilizes a small device called an Analyzer (Figure 1.) which is used to assess image quality and radiation dose for both film and digital imaging systems. This program compliments our on-site radiation safety inspections and fulfills specific regulatory requirements. The cost of this service is covered by your X-ray machine registration fee. Participation in this program is mandatory as it is a vital component of our inspection program. The data form must be completed and returned together with the test device and images, according to the instructions provided by DIQUAD.

You will receive a letter from DHHS alerting you that in about one week a packet (6 x 9-inch white envelope) containing the evaluation materials will arrive at your office. Both of these mailings will show the return address of the North Carolina DHHS. Please complete the evaluation materials and return to DIQUAD by the return date. A self-addressed, stamped envelope is provided for your use.

DHHS will send you a written report within three months advising you of how your image quality and patient radiation dose compare the dental community as a whole, and offer suggestions for improvements, if appropriate.

Figure 1. An Analyzer for evaluating intraoral image quality and patient dose. It consists of a cube (approximately 2"), a radiation dosimeter and test patterns (on top), and a dental film packet containing D- and F-speed films. For digital systems the sensor is placed on top of the film packet.



This provides a service to you as it allows you to compare the quality of your intraoral radiographs, photographic processing (if you are using film), and the radiation dose to your patients with your colleagues in the state of North

Carolina. In addition, it assists you in optimizing your intraoral image quality and patient doses.

The Radiology Compliance Branch is here to help North Carolina dentists optimize the quality of their images while assuring the dose to their patients is as low as reasonably achievable. In 2007 the Radiology Compliance Branch carried out a pilot study (see [www.nc-radiation.net/X-ray/documents/dentexlimit807.pdf](http://www.nc-radiation.net/X-ray/documents/dentexlimit807.pdf)) which showed 38% of the facilities tested had film densities which were high. This results in patient doses which are higher than necessary, especially if the film is underdeveloped. Furthermore, 35% of the facilities had low density differences which result in low image contrast, making subtle lesions difficult to detect. Low density differences are usually associated with under-processing of the film. Finally, 31% of the facilities, including those using film and digital imaging, had patient radiation doses which are higher than necessary.

The Radiology Compliance Branch evaluated 600 intraoral dental X-ray units using a dental analyzer in 2012. The most common mistakes observed by facilities were making multiple exposures and not saving the digital image with digital X-ray units. Please make one single X-ray exposure and save the digital image if you are using a digital X-ray unit.

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# Digital imaging tips for lower radiation doses and better image quality in dentistry

There are two types of digital imaging systems used in intraoral radiography – computed radiography (CR) and direct radiography (DR). CR uses a photostimulable phosphor (PSP) plate to capture the image. This plate is then scanned with a laser scanner causing the stored energy (image) to be released and subsequently captured to create the digital image. DR uses either a charge-coupled device (CCD) or complementary metal oxide semiconductor (CMOS) sensor. Both of these sensors are attached to a wire that is used to transfer the image from the sensor to a computer. The imaging characteristics of the CCD and CMOS sensors are similar. (For more information see White and Pharoah, and Parks and Williamson.)

**Patient Dose with Digital Radiography.** Patient (and staff) radiation doses with digital radiography are less than for film radiography. The patient radiation dose for CR should be similar to F-speed film, in the range of 100 to 125 mrad per image. The dose for DR should be in the range of 50 to 75 mrad per image. (D-speed film typically requires a dose of approximately 175 to 225 mrad with E-F- or F-speed film using about 100 to 125 mrad.)

**Optimizing Patient Radiation Doses.** Digital radiography requires less radiation than film radiography. A good rule of thumb is to reduce the exposure time by at least one half when chang-

ing from D-speed film to CR. For DR the exposure time reduction should be about 70%, i.e., DR requires about one-third of the exposure time as D-speed film. As an example, at 70 kVp, 7 mA, and an 8-inch source-to-skin distance, the exposure time should be less than 0.2 seconds (2/10 seconds; 200 milliseconds) for digital imaging. If the exposure time is higher than 0.2 seconds, the patient is receiving a radiation dose higher than necessary for diagnostic images.

**Image Noise.** Image noise is the fine detail variation in the image that should not be present. There are two sources of image noise in digital imaging: 1) statistical noise, and 2) structured noise.

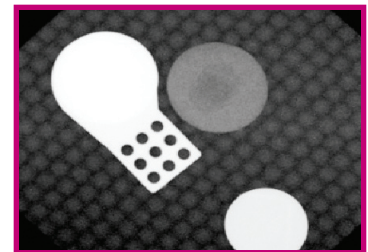
Statistical noise (sometimes referred to as quantum mottle) is observed when the radiation doses used to produce the image are low. This noise appears as a salt-and-pepper texture uniformly over the image. The appearance of statistical noise is enhanced with some types of digital imaging processing. Statistical noise can be reduced by changing the type of software filter used in image processing or by increasing the exposure time (and patient radiation dose) slightly, e.g., by 25%.

Structured noise results from structural elements in the DR sensor (see following figure). This is normally eliminated by processing the image in the computer. Structured noise often results

from replacing a sensor without making the appropriate changes in the computer processing of the image. Image processing should eliminate virtually all structured noise. (Call your equipment supplier for assistance in eliminating structured noise.)

**Image Quality.** Digital radiography has lower resolution than film imaging. However, “resolution” only measures extremely fine details in the image, details that are unlikely to be visible to the human eye without significant magnification. Digital radiography has much higher contrast (the black to white difference in an image) than film, thereby providing an equal, if not better, image for diagnostic purposes. The digital image can be manipulated by the user to improve the quality of the image.

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The structured noise (dotted or honey comb pattern in the darker areas of the image) is due to replacing a sensor without recalibrating the imaging system.

## Digital imaging tips, continued from page 17

**Additional Images Result in Additional Dose.** It is relatively easy to take additional images if the initial one is not “perfect,” e.g., the positioning is slightly off. Each additional exposure results in additional radiation dose to the patient (and staff) so taking additional images should be discouraged and done only if the image is not diagnostic.

**Exposure Latitude Can Be A Problem.** Both CR and DR imaging systems have significantly more latitude than film. Film will become black as the exposure time increases, thereby re-

quiring a reduction in time to maintain diagnostic images. With digital imaging, exposure times can be increased without a significant impact on the appearance of the image, i.e., the image becoming dark. Consequently, it is essential to monitor the exposure time to assure that it is not increased over time as increased exposure time increases the radiation dose to the patient.

Compare a reference patient digital image daily to recently exposed images to assure the proper image quality is being maintained for the same exposure time. Also, it is essential to monitor the

exposure time to assure that it is not increased over time.

**Viewing Conditions.** Digital images should be viewed on the computer display in a room with subdued lighting. There should be no overhead lights or windows with open shades. Good digital image quality will be significantly more difficult to discern with bright lighting conditions. ●

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## New Approach to the Evaluation of Intraoral Equipment, continued from page 16

This new program provides information about image quality, photographic processing, and patient radiation doses. Once this information is available, appropriate steps can be taken to correct any issues. The Radiology Compliance Branch will be available to answer your questions and assist you in optimizing your image quality and patient radiation doses.

**There are helpful tips for lowering radiation doses and getting a better image quality.**

Digital Imaging Tip: [www.ncradiation.net/Xray/documents/digimagtips.pdf](http://www.ncradiation.net/Xray/documents/digimagtips.pdf)

Photographic Processing Tip: [www.ncradiation.net/Xray/documents/photoprostips.pdf](http://www.ncradiation.net/Xray/documents/photoprostips.pdf) ●

## Photographic processing tips for lower radiation doses and better image quality in dentistry

Approximately 40% of the dental facilities in the U.S. under-process their X-ray films resulting in poor image quality and increased X-ray dose to their patients and staff. Photographic processing requires attention to certain details including:

Use the developer and fixer solutions recommended by the film manufacturer. The film and chemicals are designed to work together for optimum results. In many cases the photographic processing chemicals recommended by the film manufacturer are significantly less expensive than the competing brands.

Use the development temperature and time recommended by the film manufacturer. Film development is a time-temperature based process which impacts the speed of the film, and the density and contrast. (Some dental processors do not control the temperature of the developer, resulting in variations in film density and quality.)

The developer and fixer must be replenished regularly to maintain film density and image quality, and minimize patient dose. Eight ounces of replenisher should be added every day, even on days when films are not processed. (When films are not processed the developer solution continues to oxidize,

making replenishment necessary.) An additional eight ounces of replenisher should be added per day for each additional 30 films processed.

Never top off the chemical tanks with water!! This dilutes the chemicals, reduces film quality, and increases patient radiation dose.

Developer and fixer solutions should be changed every two weeks.

The water in the wash tank should be changed daily for up to 30 films per day. For higher volumes, the water should be changed after every 30 films. Improper washing of films will result in premature fading and staining of the images. (Some processors have water flowing through the wash tanks—the water in these processors does not have to be changed due to the continuous flow of fresh water.)

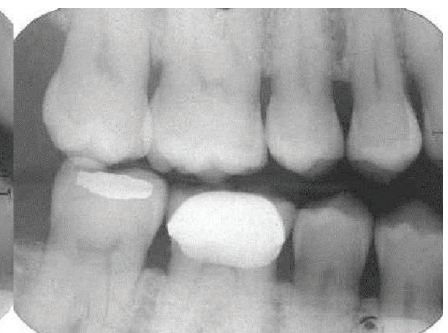
Quality Control is important for image quality and patient radiation dose. It is essential to monitor dental image quality and patient radiation dose. Image quality can be monitored simply and easily by using the inexpensive Dental Radiographic Quality Control Device ([www.xrayqc.com](http://www.xrayqc.com)). Patient radiation dose can be monitored by tracking X-ray exposure time. The X-ray exposure time should not change from day-to-day or week-to-week if the photographic processing chemicals are properly maintained.

Use E-F or F-Speed film to reduce patient dose by 40% to 50% for the same image quality!

The image quality for D- and E-F or F-speed films is the same and there is a dose reduction of 40% to 50% with the faster films! ●



D-Speed Film  
240 mrad



E-F-Speed Film  
140 mrad



# March, 2013 Newsletter Radiology Compliance Branch

Mammography, X-ray and Shielding Plans Programs  
North Carolina Department of Health & Human Services

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## Inform-a-Tech

### Radiation Safety During Pregnancy: Find out how to reduce the risk

#### A Healthy Pregnancy

Pregnancy is a wonderful time for you and your unborn baby. Ensuring your health as well as the health of your baby is essential. Eating right, exercising, taking vitamins and stopping smoking and alcohol consumption are all important considerations. It is also important to know about medical radiation procedures during pregnancy.

#### Every woman is asked an

#### important question before an X-ray

#### examination: Is there any chance

#### you may be or could be pregnant?

X-ray techs ask this question to protect the health of your unborn baby. Problem-solving or diagnostic X-rays give a doctor important, sometimes life-saving information. Like many things, X-rays have risks and benefits. Your doctor may feel that a diagnostic X-ray is needed when you're not feeling well.

#### What are the risks from X-rays?

There is little risk to a baby during regular X-rays – dental, mammogram, chest, hand, foot, or head – that do not directly expose a pregnant woman's abdomen. This is because the X-ray is focused only on the area of interest. This reduces exposure to other areas of the body. The risk of not having a needed X-ray could be much greater than the risk from the radiation. The risk to you and your unborn child is small if an X-ray is needed of your abdomen, but even small risks should not be taken if they are not needed.

#### How can I reduce the

#### risk to my baby?

You can reduce those risks by telling your doctor or X-ray tech if you are, or think you might be, pregnant, especially when an abdominal X-ray is required. Depending on your medical needs, the doctor may decide

#### not to have the X-ray exam or continue as

planned because the risk is small. Talk to your doctor about the need for an X-ray examination and understand the reason.

#### Why is this so very important?

Fetuses are sensitive to radiation during their early development, especially between weeks 2 and 15. A mother's abdomen protects her baby from radioactive sources outside her body. This means the radiation dose to the fetus is lower than the dose to the mother for most radiation exposure.

#### It is important for women who are

#### concerned about radiation exposure to their

#### unborn babies to talk with their doctor.

#### All employees, students and business associates of any hospital or medical

#### facility are accountable to HIPPA regulations.

#### What information is protected?

- Information that would identify an individual (patient).
- Any information that relates to a patient's health, treatment or finances.

#### Are my answers to a doctor's

#### questions during an X-ray

#### procedures protected?

Yes. Anything you discuss with your doctor is protected under the Federal Health Insurance Portability and Accountability Act, or HIPPA. This federal law protects medical information, regardless of how it is collected (verbal, written and electronically). All information given during your visit to an X-ray tech or doctor is protected under this policy.