



# Newsletter Radiology Compliance Branch

## Mammography, X-ray and Shielding Plans Programs

December 2011

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

# New Department and Division, Same Purpose

The Radiation Protection Section recently moved to a new department and division. Our physical location is the same, however we are now in the Department of Health and Human services and the Division of Health Service Regulation. This change came about as a part of the Governor’s reorganization to make state government more efficient.



Photo of Radiation Protection Section office building. courtesy Google maps, 2007

Radiation Protection had historical ties to this Department because it began in this Department when it was called the Division of Facility Services. In 1993, with the

beginning of the mammography program, the agency contracted with DFS to perform mammography inspections which led to establishing the mammography program for North Carolina.

This transition allows radiation protection the opportunity to fulfill the same purpose and to continue our mission to protect the health and safety of all North Carolinians. We will continue to deliver the same services, values and goals to our citizens. ●

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# About the Radiation Protection Section

North Carolina General Statute in section 104-E are the enabling legislation for the mission and duties of the Radiation Protection Section (RPS). Under these statutes, RPS administers the following programs in order to provide protection from the harmful effects of radiation for workers and the public: a Radon monitoring, mitigation and education program; an emergency response program for nuclear facilities; an environmental monitoring program; a radioactive material licensing, compliance and education program; a low level radioactive waste management oversight program; a progressive Homeland Security initiative; an effective radioactive material emergency response program; an X-ray registration, compliance and education program; a mammography registration, compliance and education program; a tanning registration, compliance and education program; an information resource location for other sources of non-ionizing radiation; and a comprehensive enforcement program.

Under the auspices of the Radiation Protection Commission, RPS strives to maintain a healthy balance between regulatory responsibility, environmental stewardship and customer service. The RPS staff members are continually striving to streamline processes and offer the regulated community every opportunity for compliance with the regulations in 15A NCAC 11. When an inspection reveals compliance issues, the facility is responsible for compliance; however, RPS will provide continuing support throughout the process so that the facility can learn more fully what is expected. If that process fails to deliver the required level of protection for the health and safety for workers and the public, RPS has an effective and fair enforcement program that can be engaged, if necessary, to ensure the safe use of sources of radiation. ●

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## Inform-a –Tech program

Inform a tech, is a comprehensive program on who, what and when of pregnancy and x-rays. Even though the program was just implemented in mid 2011, it has been on my mind and in my heart for the past five years, almost my entire employment within the State of North Carolina. It came about with one question; “How do you ask a patient if she’s pregnant?”

The Inform a tech program is available in four parts.

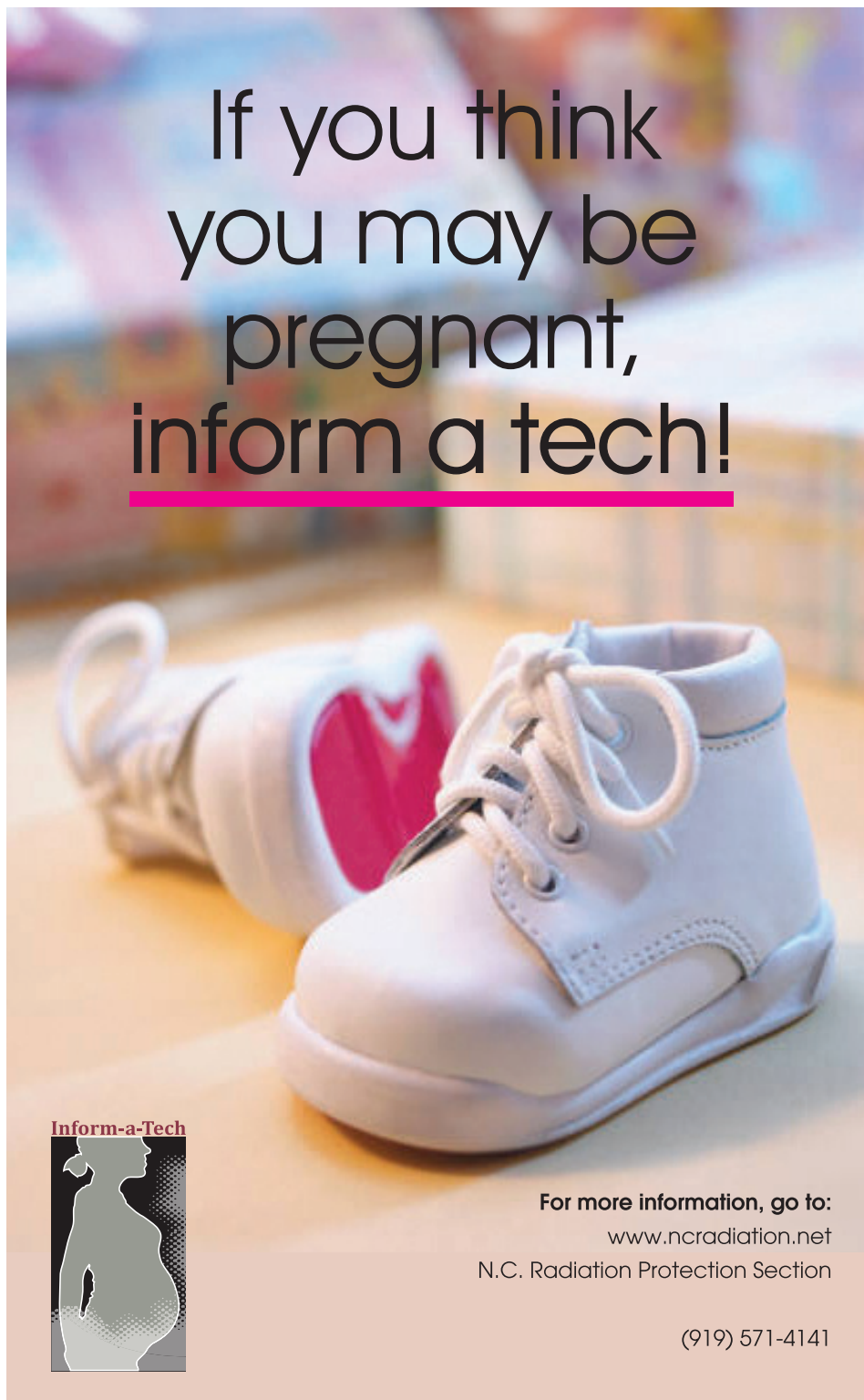
### 1. **Poster:**

Reflects the joy of motherhood without depicting a baby or a pregnant woman. It is very simple, yet elegant, with a powerful message.

### 2. **Pregnancy Education :**

pamphlet to explain to women why we ask this question, why we will always ask this question, and why we may ask it several times during a single visit to an Imaging

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If you think  
you may be  
pregnant,  
inform a tech!

For more information, go to:  
[www.ncradiation.net](http://www.ncradiation.net)  
N.C. Radiation Protection Section

(919) 571-4141

## Inform-a-Tech, continued from page 3

(x-ray) department.

**3. A power point presentation** to aid in continuing education efforts for facility and for facilities who hire persons not registered with the ARRT and have no formal education in radiation safety, this presentation can aid in the educational requirements for training. It can also be used as part of an overall radiation safety program.



## **4. And finally, we have a logo:**

This logo will be an integral part of the Inform-a-Tech program and our efforts toward radiation safety for pregnant women.

Are you pregnant and about to have an x-ray examination? Or maybe you're pregnant and work with x-radiation, "Is that radiation exposure likely to affect the baby's development and its future health? The qualified answer is most likely "no".

In our endeavor to minimize radiation exposure, we accept the premise that any exposure to ionizing radiation carries a risk.

Clearly, avoidance of radiation exposure is a sensible approach when dealing with radiation safety and the possibility of compromising the health of a mother and her baby.

The poster, pamphlet and presentation are now available for all of our customers to download from our website, [www.ncradiation.net](http://www.ncradiation.net) ●



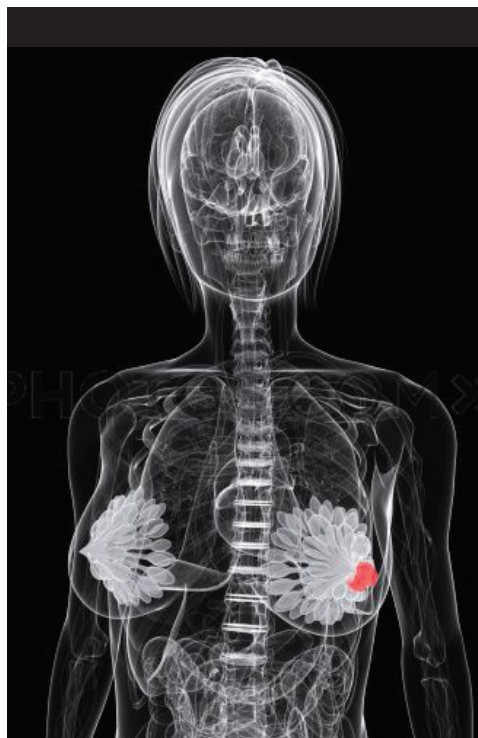
## Methodology questioned

# Task Force recommendations cause confusion

A November 2009 U.S. Preventive Services Task Force report left many women confused about when they should get their mammogram. This report announced that women age 40-49 no longer need to be screened for breast cancer and that women 50 and older only need screenings every second year. The Task Force report has been criticized by many experts, and its conclusions are contradicted by many clinical studies done in the United States and abroad that prove the benefits of mammography.

Some specific flaws are outlined below:

- The Task Force did not involve breast cancer experts in their studies (such as breast surgeons, oncologists, and radiologists).
- They used data from older and poor quality studies that included poor mammography techniques and outdated technology, significantly biasing the results.



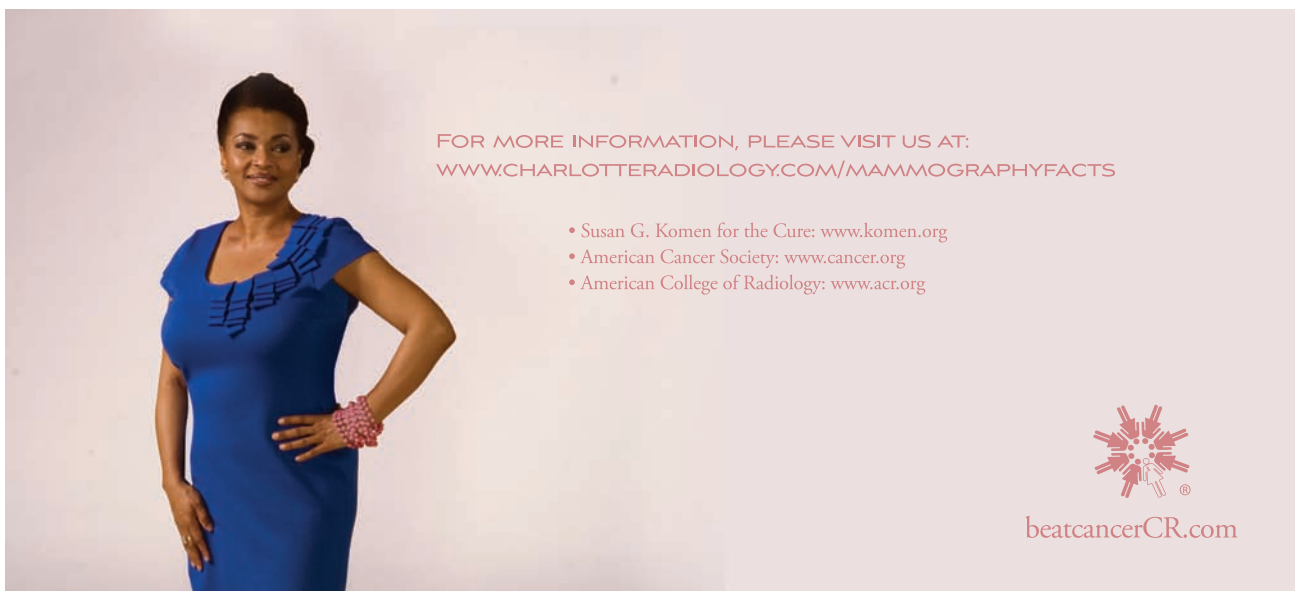
- They did no direct research, but used computer models to estimate screening mammography benefits at various ages. This approach is less reliable than the “gold standard” used for most medical research – a randomized, double-blind study measuring actual outcomes. Their results directly contrast those found in carefully designed trials showing significant mortality reduction due to screening women ages 40+ and improved treatments.

- The Task Force overstates the “harms” of screening mammography, suggesting that additional testing may cause anxiety and in convenience. They ignore the anxiety a woman may face by being deprived of needed cancer screening or the burdens and costs to a woman who develops a later stage, more lethal cancer requiring more extensive treatments due to the lack of early detection.
- The Task Force suggests only screening women under 50 whose families have a history. However, approximately 75 percent of women diagnosed with breast cancer have no family history of the disease. Limiting screening to those with risk factors will not detect the majority of breast cancers.

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## Methodology questioned continued from page 5

The recommendation from breast health experts are consistent. Forty is the age to schedule your first mammogram and start an annual routine. Since 75 percent of women with breast cancer have no family history, there's no reason to wait.



## **Early detection saves lives.**

The preceding excerpts were taken, with permission from, "40 is the New Pink", campaign from Charlotte Radiology, "40 is the New Pink campaign reproduction rights belong to Charlotte Radiology" ([www.charlotteradiology.com/pdfs/40isthenewpink.pdf](http://www.charlotteradiology.com/pdfs/40isthenewpink.pdf)) ●

## Dr. Oz says...

Dr. Mehmet Cengiz Oz MD is a specialist in thoracic and general surgery in New York, New York. He has been a practicing surgeon for 25 years, having graduated medical school from the University of Pennsylvania School of Medicine and doing his Internship, Residency, and a fellowship at the Columbia Presbyterian Medical Center.

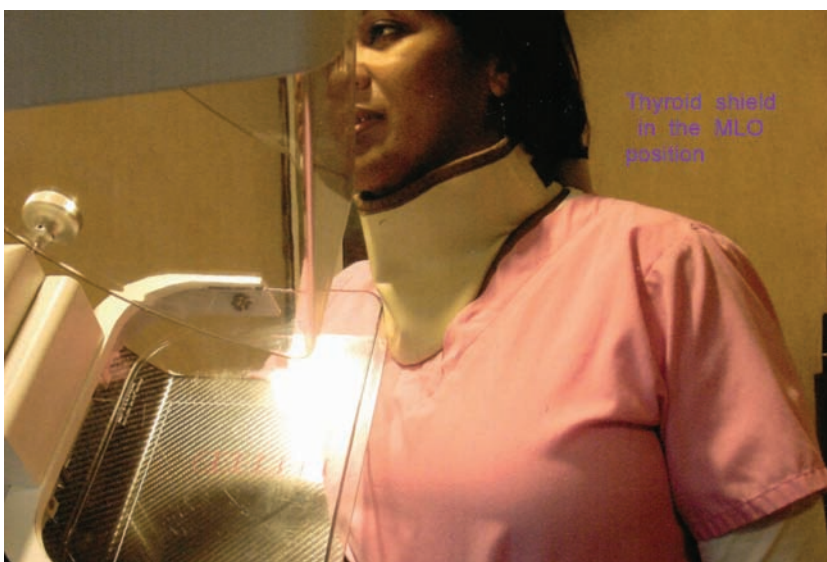
So, when Dr Oz says anything about weight loss and exercise, I'm there. I haven't lost much weight, but I'm not consistent when it comes to exercise or diet.

Dr. Oz says...Women should request the use of a thyroid shield when having their annual mammogram. This statement affected all of the mammography community, he and erroneous media reports have caused great concern and some panic within the general population, who because of Dr. Oz, believe the small amount of radiation from breast imaging may increase their chance to develop thyroid cancer. Their concern is not supported scientifically or within the professional community of mammographers and Radiologist who specialize in breast imaging and diseases of the breast.

Radiologist and breast imaging specialist pointed out the

senselessness of Dr.Oz's advice, since we know radiation exposure to the thyroid gland after all these years would be less than the background radiation received by watching his show.

What is proven, thyroid shielding can affect the diagnostic quality of a mammogram, and compromise the images, requiring a retake and doubling the amount of radiation exposure to the breast, to the patient and thyroid. Dr. Oz is good, but he's not the great and wonderful wizard. ●



## MQSA National Statistics

The FDA maintains and updates the MQSA Scorecard with the most commonly requested national statistics regarding the MQSA program. ●

<b>Certified facilities, as of October 1, 2010</b>	<b>8,652</b>
<b>Certification statistics, as of October 1, 2011</b>	
Total certified facilities / Total accredited units	8,620 / 12,299
Certified facilities with FFDM2 units / Accredited FFDM units	6,895 / 9,976
<b>FY 2011 inspection statistics, as of October 1, 2011</b>	
Facilities inspected	8,328
Total units at inspected facilities	11,481
Percent of inspections where the highest noncompliance was a:	
Level 1 violation	0.5%
Level 2 violation	13.8%
Level 3 violation	2.6%
Percent of inspections with no violation	83.0%
<b>Total annual mammography procedures reported, as of October 1, 2011</b>	<b>39,098,089</b>



# CT Brain Perfusion Exposure Survey

In January of this year the Radiology Compliance Branch partnered with the Conference of Radiation Control Program Directors (CRCPD) and participated in a national health and safety survey of radiation dose and scanning procedures for CT brain perfusion studies used for stroke evaluation. The survey was part of an ongoing investigation by the U.S. Food and Drug Administration into reported cases of excessive radiation exposure during CT brain perfusion studies.

In the initial phase of the survey eleven hospitals in North Carolina reported that they are currently performing CT brain perfusion studies. Each of the eleven hospitals participated in an onsite survey during the month of January. Results of the onsite

surveys showed that patient radiation dose levels at some of the facilities were above the expected level of 0.5 Gy CTDIvol for this type of study. Subsequent follow-up surveys to date show that these hospitals are now currently performing CT brain perfusion studies within the FDA's recommended radiation dose guidelines.

The FDA recommends that each facility set its own alert level for brain perfusion studies. Exceeding an alert level requires careful review before proceeding and also necessitates additional action by the user. Alerting the user lessens the likelihood of acute injury to the patient such as erythema or epilation. Accordingly, the FDA has suggested an alert level of 1 Gy CTDIvol which is about half the dose associated with the early signs of skin injury.

In addition, FDA's Medical Device Reporting (MDR) Regulations of 21 CFR Part 803 requires hospitals and other facilities to report adverse events associated with the use of medical devices. If such an event is identified, health care professionals should follow the reporting procedures at their facility. Adverse events should be reported directly to the manufacturer or to MedWatch, the FDA Safety Information and Adverse Event Reporting Program <http://www.fda.gov/Safety/MedWatch/default.htm> or to the FDA by phone 1-800-FDA-1088. More information on CT brain perfusion studies can be found on the NC Radiation Protection Section X-ray Program CT Public Information link. ●

# Shielding Plans Process Improvement

The number of shielding plans submitted to N.C. Radiation Protection has grown over the years. In order to improve the delivery of services with continuity of service we have begun to make changes in the processes. We now have a team of reviewers with centralized processing of all shielding plans. We added an e-mail box for direct delivery of plans for processing along with a new e-form. Plans still can be mailed or faxed but the e-mail box allows the qualified expert to deliver plans electronically. There is a two week turn around processing time. We encourage registrants to plan and allow adequate time for processing of the files by the agency.

The agency has made the determination that plans on mammography units, bone density units, and on therapy rooms containing x-ray equipment that have a current radioactive material license are no longer needed. In each of these situations, all other rules apply including x-ray registration, a post install radiation survey, a report of installation and inspections.

To improve awareness and education, our reference guide has been updated to assist both the registrants and qualified experts who prepare the shielding plans. The “Shielding Plan Review and Post Installation Survey Requirements” document is a guide to assist facilities and service providers in submitting shielding plan reviews to RPS.

We are working to standardize the review process with a team of reviewers. The shielding design form has been modified to assist in this process for both the internal and external customer. The “e-form” can be completed online and printed for submission. If you would like to email your form and plans you can:

- 1. Complete the form online**
- 2. Save a copy of the completed form on your computer**
- 3. Click the “shielding plan review mailbox” link on the form**
- 4. Attach your form and plans then send the documents.**

The form and reference guide is located on our website at [www.ncradiation.net](http://www.ncradiation.net). Please refer to our website for specific details regarding requirements of shielding plan review when replacing equipments. ●

## New E-mail Box for Installers and Qualified Experts

As we continually strive to improve processes and processing of documents we have added two new e-mail addresses to make it more expedient for qualified experts and installers to submit required forms. We are moving towards electronic records and this is one more step in that direction.

### Qualified Experts:

Should submit the e-shielding plan form to [shieldingdesign@dhhs.nc.gov](mailto:shieldingdesign@dhhs.nc.gov)

### Service Providers:

A copy of the federal "Report of Assembly of a Diagnostic X-ray System, Form FDA 2579" and any other notifications required by .0206 should be submitted by persons engaged in the business installing radiation machines and components or who are in the business of furnishing any equipment services. These notifications or forms should be submitted to [fda2579@dhhs.nc.gov](mailto:fda2579@dhhs.nc.gov)

### "15A NCAC 11 .0205

#### APPLICATION FOR REGISTRATION OF SERVICES

(a) Each person who is engaged in the business of installing or offering to install radiation machines and machine components or is engaged in the business of furnishing or offering to furnish any equipment services listed in Paragraph (d) of this Rule in this state, to any agency licensee or registrant, shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services."

### "15A NCAC 11 .0206 REPORTS OF INSTALLATION

(a) Persons, registered pursuant to Rule .0205 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install radiation machines in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .0111 of this Chapter, of:(1) whether any radiation machines were installed, transferred, or disposed of during the calendar quarter; (2) the name and address of persons who received radiation machines during the calendar quarter; (3) the manufacturer, model and serial number of each radiation machine transferred or disposed of; (4) the date of transfer of each radiation machine.

(b) The information specified in Subparagraphs (a)(2), (3) and (4) of this Rule may be omitted from the quarterly reports required in (a) of this Rule for any diagnostic x ray system which contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency." ●