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# North Carolina Radiation Protection **News** section

2014 - 2015

FALL / WINTER EDITION



## A Culture of Safety

...inspecting individuals and organizations performing regulated activities to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities.

RALEIGH - Governor Pat McCrory has declared November as Radiation Safety Month. It is a time to celebrate the discovery of X-rays 119 years ago, to honor radiation protection professionals, and to elevate awareness of the importance of safety in the many uses of radiation and radioactive materials that benefit thousands of North Carolinians every day. The proclamation can be viewed at [www.governor.state.nc.us/newsroom/proclamation/20141101/radiation-safety-month](http://www.governor.state.nc.us/newsroom/proclamation/20141101/radiation-safety-month).

Radiation safety is a collaborative effort that involves the citizens who receive services, healthcare providers, imaging professionals, and radiation workers who provide licensing, educational services and guidance to help keep exposures within safe limits.

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“Conrad Roentgen discovered X-rays on Nov. 8, 1895, and radioactivity was discovered in March of 1896.”

# News Release

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The Department of Health and Human Services, through its Radiation Protection Section, promotes an awareness of a radiation safety culture that emphasizes finding all opportunities to reduce radiation dose where warranted.

The Radiation Protection Section oversees/regulates/provides guidelines on the use of ionizing radiation in X-ray, mammography and radioactive materials facilities in North Carolina. It also educates the public regarding the dangers of radon gas. North Carolina has more than 7,800 registered X-ray devices, 236 mammography facilities, 2,090 radioactive material facilities and 1,184 tanning facilities.

In conjunction with Radiation Safety Month, DHHS and the Radiation Protection Section created a web page to provide information on radiation exposure. For each type of non-ionizing radiation, the current scientific and medical information is discussed, along with regulations in the U.S. The non-ionizing webpage is available



“ N.C. has more than 7,800 registered X-ray devices, 236 mammography facilities, 2,090 radioactive material facilities and 1,184 tanning facilities. ”

at <http://ncradiation.net/NonIonizing/NonIonizing.htm>. The range of devices that may cause exposure includes tanning beds, cellular phones and microwave ovens. Such devices emit non-ionizing radiation such as ultraviolet

used in tanning beds, infrared used in lasers, radio frequency used in broadcast antennas and cell phones, and extremely low frequency such as alternating current (AC) electricity in transmission lines, and video display terminals. ●

## General Information

### Want to be informed? Subscribe to Be in the know?

All correspondence from the agency goes out to our subscribers electronically through the listserve. Click on the links below to stay current with notifications, newsletters and information that is pertinent to your facility. Newsletter/notification listserves have been created! To subscribe, go to:



X-ray Program News  
<http://lists.ncmail.net/mailman/listinfo/xraynews>

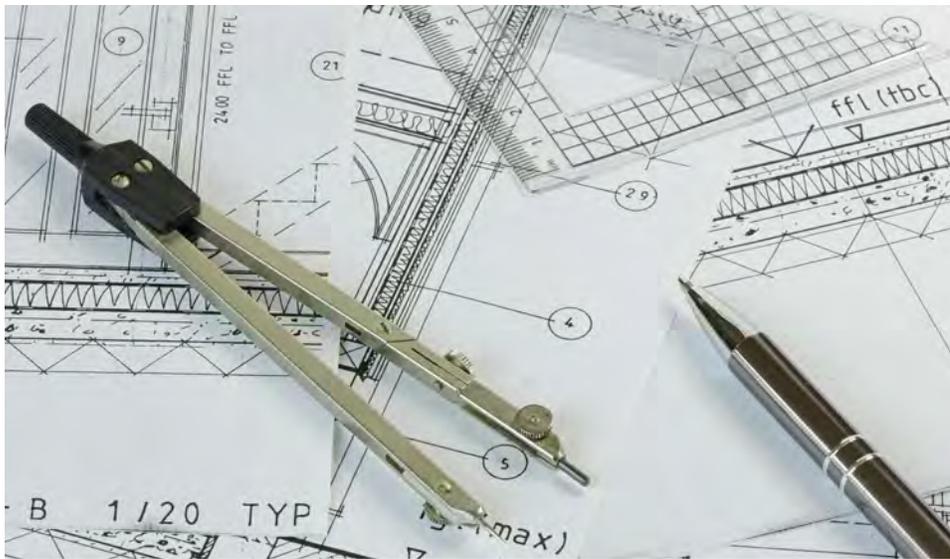


Mammography News  
<http://lists.ncmail.net/mailman/listinfo/mammographynews>

CHECK OUT OUR WEBSITE!

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

## Frequent Questions Asked by Registrants



## GENERAL INFORMATION

You can now download and print the following from our website at [www.ncradiation.net/Xray/inspections.htm](http://www.ncradiation.net/Xray/inspections.htm)

- Radiation Safety Program Guide (replaces old versions of model guide)
- Radiation Safety Program Assessment Tool (same tool inspectors use can be used by the facility for self-evaluations)
- Inspection Checklist for Medical Imaging, CT and for Non-Healing Arts (industrial, analytical)
- Reference Guides: We developed reference guides to answer most of the common questions asked.



### Q: What is a radiation survey versus a shielding design?

A: Both the shielding design and 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. Additionally, it includes a drawing of the room with scatter measurements demonstrating the shielding integrity.

### Q: Can I fax in my application of registration or updated NOR?

A: No, we no longer receive faxed documents as of 6-20-14. We have provided a service email box, [XrayNORS@dhhs.nc.gov](mailto:XrayNORS@dhhs.nc.gov), so that you can now email your NOR to our agency. You must remember to sign and date the forms. All fields should be completed to prevent delays in review and processing.

### In Need of Regulations, Forms or Want to Make Sure Your Copy is the Current One?

Signs and postings are a click away, just check out our website [ncradiation.net](http://www.ncradiation.net) for required forms, signs and postings which can be printed from the website.

Required postings can be printed from <http://www.ncradiation.net/Xray/postings.htm>

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# Frequent Questions Asked by Registrants

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## **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. This includes equipment bought through the internet. The seller must be a registered service provider with the state of North Carolina. The RCB Web site, [www.ncradiation.net/Xray/service.htm](http://www.ncradiation.net/Xray/service.htm), contains a current list of all North Carolina registered service providers.

## **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.



“ Updated copies of the rules can be maintained electronically and available to your staff or printed from our website [ncradiation.net](http://ncradiation.net). ”

## **Q: I am a new owner of a practice that is either new or pre-existing. What do I need 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 website. 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: 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: Where does a registrant locate the most current copy of regulations?**

A: Radiation Protection's last printed copy of the regulations was in October 2002. Since that time rule changes have impacted x-rays such as .1004. This impacts reporting to individuals regarding dosimetry readings which was effective in January 2013. Updated copies of the rules can be maintained electronically and available to your staff or printed from our website [ncradiation.net](http://ncradiation.net).

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

A: According to 15A NCAC11 .0603(a)(G), deliberate exposure of an individual for training demonstration or other non-healing arts purposes is prohibited. ●

# GENERAL INFORMATION

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- Notice to Employees (recently updated)
- Caution Signs for Healing Arts (medical, dental, chiropractic, podiatry and veterinary)
- Caution Signs for Non-Healing Arts (industrial and analytical)
- Current Regulations: [http://ncradiation.net/all\\_rules/15ahome.htm](http://ncradiation.net/all_rules/15ahome.htm)

## Other helpful printable documents from our website:

- Pregnancy Poster (Inform A Tech or Inform Your Dr.)
- Template for Dental Technique Chart
- Fluoroscopy Posters to educate your staff:
- 10 Pearls: Radiation protection of patients in fluoroscopy
- 10 Pearls: Radiation protection of staff in fluoroscopy

## Region Inspection Staff

Our staff are based in regions to better serve the needs of the registrants. You can contact your regional inspector by clicking on the link: [www.ncradiation.net/Xray/NCcounty%20map2013.pdf](http://www.ncradiation.net/Xray/NCcounty%20map2013.pdf).

Find your region on the color-coded map to identify your inspector and their contact information. They are available to answer specific questions. Our inspectors can do some group presentations in their regions. ●

## Who can order X-Rays?

Can x-rays be used to make exposures of individuals for training or non-healing arts purposes?



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



(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); (G) 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.

The answer is in **15A NCAC11 .0603(a)(1)(G)**- X-Ray exposures must be authorized by a licensed practitioner. The N.C. Medical Board has additional requirements calling

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# Who Can Order X-Rays?

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for the licensed practitioner to be licensed in North Carolina and that the NCMB defines the scope of practice for a licensed practitioner. The scope of practice questions should be directed to the appropriate regulating licensing boards such as medical, chiropractic, podiatry, dental and veterinary.

Further guidance on Physician orders can be found in our reference guide [www.ncradiation.net/Xray/documents/orderxrays.pdf](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 and have it dated and signed by the physician.

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. ●

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## Rule Change to Reporting Doses to Workers



An amendment was made to regulation 15A NCAC 11 .1004 which became effective

on January 1, 2014. The regulation places stronger emphasis on annually reporting the dose to individuals working in radiation. Registrants are required to report an individual's occupational dose when it exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue within 30 days of the request. The facility's operating procedures should define the registrant's dose reporting process to workers as indicated in this regulation.

### 15A NCAC 11 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

(a) Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to rules of this chapter, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this Chapter. Each notification and report shall:

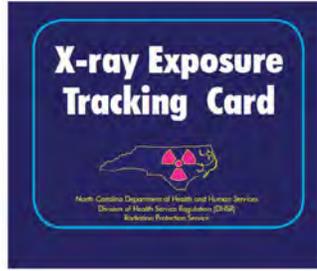
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**15A NCAC 11 .1640:**  
Records of Individual Monitoring Results

**15A NCAC 11 .1646:**  
Notification of Incidents

**15A NCAC 11 .1647:**  
Reports of Radiation Exceeding the Limits

**15A NCAC 11 .1648:**  
Reports of Planned Special Exposures



“ Include the dates and locations of work under the license or registration in which the worker participated during this period.”

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(1) be in writing;

(2) include identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) include the individual's exposure information; and

(4) contain the following statement:

This report is furnished to you under the provisions of Section **15A NCAC 11 .1000: NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS.** You should preserve this report for further reference.

(b) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of **Rule .1640** of this Chapter. The licensee or registrant shall provide an annual report to each individual monitored under **Rule .1614** of this Chapter of the dose received in that monitoring year if:

(1) the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) the individual requests his or her annual dose report.

(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials. The report shall:

(1) be furnished within 30 days from the time any request is made, or within 30 days after the information has been obtained by the licensee or registrant, whichever is later;

(2) cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and

(3) include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to **Rules .1646, .1647, or .1648** of this chapter to report to the agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the agency. The reports shall be transmitted at a time no later than the transmittal to the agency. ●



## Service Providers and Registration



Registrants and licensees must use companies and individuals which are registered service providers with the Radiation Protection Section. Service providers are companies and individuals which offer sales of radiation equipment and components or provide radiation related services to registrants or licensees.

Radiation equipment sales include:

- Direct sales of radiation machines or components.
- Online or catalog sales of radiation machines or components.

Radiation related services include:

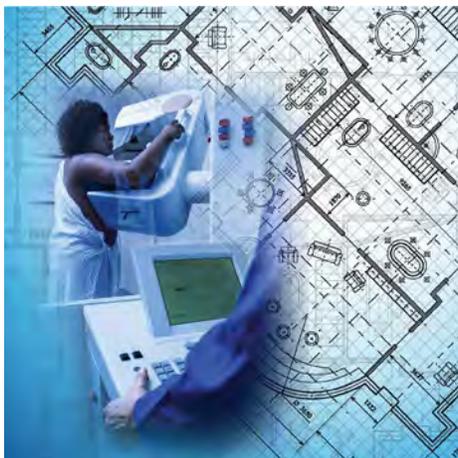
- Installation or service of radiation machines or components.
- Shielding design.
- Radiation surveys and shielding evaluation.
- Calibration of radiation detection equipment.
- Personnel dosimetry services.
- Health physics consulting.

Registrants or licensees should be careful with online purchases of radiation equipment. Some equipment for sale online may not be approved for healing arts use or may be unsafe. You may confirm the registration status of a service provider by reviewing the list of approved providers at

[www.ncradiation.net/Xray/service.htm](http://www.ncradiation.net/Xray/service.htm).



## Shielding Plans in Mammography



The Radiation Protection Section stopped requiring facilities to submit shielding plans for mammography equipment on July 1, 2011. This change was based on the Section's review of years of existing plans, and the lack of extra shielding recommended in those plans.

Digital breast tomosynthesis (DBT) is a new mammography technology that is being added to facilities in NC. DBT equipment typically requires

additional exposures than traditional mammography equipment and may have higher radiation output because of this. To ensure installation of this equipment is properly shielded, the Section is requiring facilities that add DBT equipment to submit a shielding plan for review prior to installation. A shielding plan is also necessary for upgrading an existing digital machine to DBT capability.

The Section will monitor the plans submitted for DBT equipment and review this policy based on the recommendations listed in these plans.

Note: Installation of breast stereotactic equipment continues to require submission of shielding plans to this Section. Currently, only standard mammography and bone density equipment are not required to submit plans. ●



## Reports of Sales and Installations of X-Ray Systems



“ The reports may be mailed or submitted by email to [FDA2579@dhhs.nc.gov](mailto:FDA2579@dhhs.nc.gov). ”



Sales and installations of X-ray systems by service providers are required to be reported to RPS. This may be accomplished by submission of the FDA Form 2579 when applicable. Sales and installations by service providers, not reported on FDA Form FDA 2579, should be reported to NC RPS within 15 days following the sale/installation on the Report of Sale or Installation of X-Ray Systems form. The reports may be mailed or submitted by email to [FDA2579@dhhs.nc.gov](mailto:FDA2579@dhhs.nc.gov).

This form is not for use by X-ray registrants. It is only for service provider companies that sell, install and dispose of x-ray systems for use within the state. ●

## OUT-OF-STATE MOBILE UNITS



The North Carolina Regulations for Protection Against

Radiation require that any person bringing a radiation machine(s) into North Carolina, for either temporary or extended use, shall provide a written notice to the Radiology Compliance Branch (RCB) in the Radiation Protection Section.



All out-of-state equipment registrants to include those who engage in industrial radiography and analytical equipment use MUST complete Mobile Equipment Location Report form. Our agency MUST receive completed forms five work days before entering the state to ensure meeting compliance standards. Completed forms should be submitted to [XrayService@dhhs.nc.gov](mailto:XrayService@dhhs.nc.gov). ●

# The Future of Personnel Dosimetry



The most significant personnel doses in the hospital environment

often occur in the interventional suite where fluoroscopy is performed. Recent studies have shown hospital workers who are routinely exposed to ionizing radiation in the interventional suite are at an increased risk for cancer, cataracts and other health problems. Such reports have forced radiation safety professionals to look for a more effective method to reduce personnel exposures. In the past, health and medical physicists relied primarily on training and the use of shielding to reduce personnel exposures, and then reviewed passive dosimeter results months later to hopefully see a dose reduction. However, as interventional techniques have



become longer and more complicated, our reliance on retraining and reviewing delayed results from passive dosimeters (if actually worn by staff), is recognized by many as ineffective. Some hospitals have tried to use electronic active dosimeters to monitor staff exposures during interventional procedures to obtain a better understanding of the dynamics of staff dose. However, the use of such devices has been met with limited success. Some electronic dosimeters are not capable of accurately monitoring cumulative exposure in a pulsed radiation field, as found in the fluoroscopy suite. Some are too heavy and uncomfortable to wear, and all electronic dosimeters require the user to retrieve and view the LED display which can be difficult to read. As a result, efforts to achieve ALARA for staff doses in the interventional suite have been challenging and largely unsuccessful.

A few companies saw the need for a better dosimeter and have developed products to overcome the limitations of passive dosimeters and conventional electronic dosimeters. For example, one company introduced a real-time

dose monitoring system with personal dosimeters that wirelessly transmits cumulative exposure and exposure rate data to a display monitor that is the centerpiece of every interventional suite. Displaying each individual's cumulative exposure and exposure rate data on the monitor allows each individual to make real-time adjustments in their location or shielding and immediately see the results of their efforts to achieve ALARA during interventional procedures. These types of dosimeters are also making their way into the legal dosimeter market. One company is introducing a NVLAP-accredited device which wirelessly transmits

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## The Importance of Personnel Monitoring



“ Currently the natural incidence of cancer in the United States is 1 out of every 3 persons. ”



Digital and conventional x-rays produce radiation which is undetected by human senses. Low levels of ionizing radiation emitted from x-ray machines used in dental and other offices could represent a potential health hazard over time. How will you know if you or your staff is at risk of exposure? Dosimeters (radiation badges) can easily be used to monitor exposure levels.

### Radiation Litigation: Be prepared

Heredity, stress, pollution and radiation have the potential of increasing one’s likelihood of getting some form of cancer. Currently the natural incidence of cancer in the United States is 1 out of every 3 persons. What portion of workers will associate that cancer with their past exposure to ionizing radiation received from their work environment? What percentage will initiate litigation? One way to protect and secure your business is to adequately utilize radiation

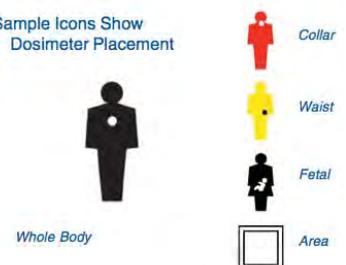
## The Future of Personnel Dosimetry

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exposure data as the wearer passes within a certain distance of a “hub”, thus allowing institutions to automatically collect exposure data and readout periodically- such as monthly- without the burden of frequent collection and distribution. Plans for this device include monitoring for gamma, beta and neutron radiation exposure.

The primary challenge facing real-time dose monitoring is in pricing to compete with passive dosimetry. However, as any Radiation Safety Officer knows, the more significant cost of a dosimetry program lies not in the cost of the dosimeters, but in the time and resources needed to collect and distribute dosimeters on a monthly and quarterly basis, as well as in the unpopular task of chasing after unreturned badges. Anything which can reduce or remove this administrative burden would be welcomed. Although it appears that real-time personal dosimeters will have some catching up to do to compete with passive dosimeters, the move from passive dosimeters being used only “to demonstrate compliance” to the use of active dosimeters to “demonstrate compliance AND achieve ALARA” is fast approaching. ●

Sample Icons Show Dosimeter Placement



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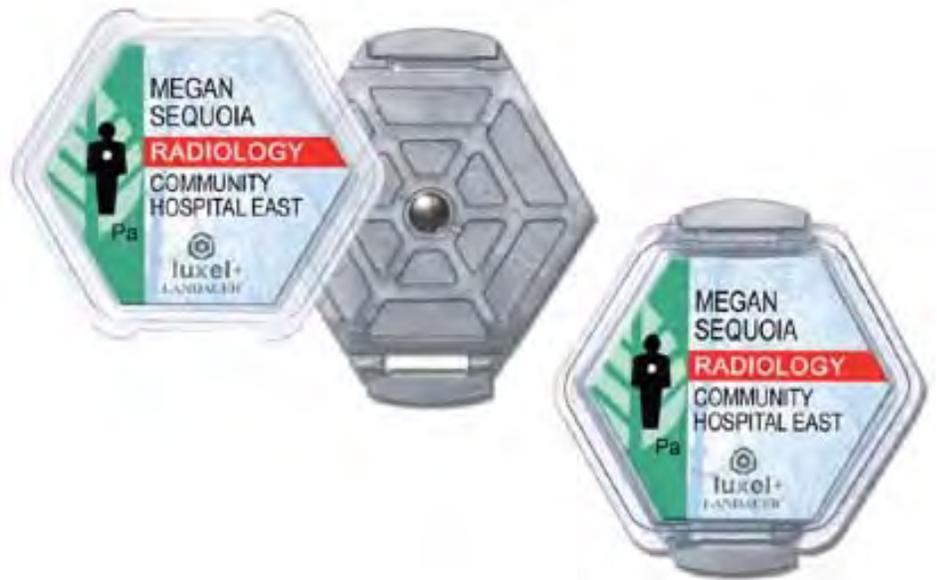
# The Importance of Personnel Monitoring

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monitors. The records maintained as a result of using this method will provide some proof that the office environment was within safe and legal limits.

## Protect Your Practice with Radiation Exposure Reports

The radiation reports provide complete documentation of individual radiation doses. A record of consistent safe exposure levels will prove valuable if a question emerges regarding radiation safety. By using personnel monitors, your staff can be assured of a safe working environment and know that their employer cares about their health and safety. ●



## Optically Stimulated Luminescence (OSL) Dosimeter

“ Rule .1614 MONITORING OF INTERNAL AND EXTERNAL OCCUPATIONAL DOSE ”



- (1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
- (a) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in Rule .1604(a) of this Section. (500mR in a calendar year)
  - (b) minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the applicable limits in Rules .1609 or .1620, and

- (c) individuals entering a high or very high radiation area

There are two main types of dosimeters currently in use. One type is a Luxel filmstrip dosimeter model. This is referred to as a badge dosimeter. This type of badge is worn for a predetermined cycle and is then sent to the company to be read. The other type is an optically stimulated luminescence dosimeter (OSL) model. This type of badge is fairly new to personal dosimetry badges. An OSL can supply an instant readout. There are several companies that manufacture OSL dosimetry badges.

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# Optically Stimulated Luminescence (OSL) Dosimeter

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## OSL Badges

This type of badge is not sent to the company to be read, but is read by inserting it in a USB port on the computer. Once the computer is connected to the internet, this device immediately supplies the user with his/her dose readings.

According to one manufacturer, an OSL dosimeter provides radiation workers with a precise measurement of radiation dose and long-term exposure tracking. A built-in memory chip stores each user's identity via embedded, unique serial code that is assigned to the user. Once an account is set up for the user, the

user may view their dose at any time by logging into their account and plugging the badge into a USB port and following the directions.

While an OSL monitor can be read at any time, the reports must be read at minimum of quarterly. The reports must be stored in such a manner that an inspector can view the records during an inspection. The reports must be stored on the computer and accessible to the employees. If a physical copy is preferred, the reports may be printed in addition to being stored in an employee-accessible drive on the computer. The dosimetry reports must be kept as long as the facility is registered and is in practice.



Regardless of the type of dosimeter the facility chooses to use, the guidelines are the same. A dosimetry badge should be worn near the collar bone and chest area, which is most likely to receive the greatest amount of radiation. Wear the badge so that the front is facing the source of radiation. If a lead apron is worn, wear the badge at the collar level on the outside of the lead apron. Only wear the badge that is assigned to you. Do not intentionally expose your dosimeter to radiation or wear your badge when you are a patient having medical or dental x-rays. The badge must be worn by the person to whom it is assigned. When not wearing the badge, maintain and store it in a radiation-free area.

A control badge is unnecessary when using OSL badges. All suppliers of radiation dosimetry badges must be NVLAP-accredited and registered with the State of North Carolina. ●

# Diagnostic Reference Levels



**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 giving a radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. Diagnostic reference levels are determined based on data collected from nationwide studies such as the Nationwide Evaluation of X-ray Trends (NEXT) Program and are

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## Laser Safety

“There are, however, some significant hazards that users should be familiar with in certain types of laser equipment.”



The increasingly widespread use of lasers requires more people to become familiar with the potential hazards associated with the misuse of this valuable product of modern science. Lasers are used in many applications including material processing, construction industry for cutting and welding materials, medical applications such as laser surgery and various skin treatments, communications, energy production and national defense in devices for marking targets and measuring range and speed, scientific applications such as research and development and in laser lighting displays as a form of entertainment medium. From a safety

consideration it is the introduction of laser devices into more consumer oriented retail products such as laser scanning devices, copy and printing machines and CD/DVD computer applications. Most of these devices emit relatively low power levels, contain enclosed beam systems and pose no laser hazard.

### Laser Hazards:

There are, however, some significant hazards that users should be familiar with in certain types of laser equipment. Current lasers emit beams of optical radiation. Optical radiation (ultraviolet, visible, and infrared) is termed non-ionizing radiation to

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## Laser Safety

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distinguish it from ionizing radiation such as x-rays and gamma rays, which are known to cause different biological effects. X-ray lasers are now under development but are limited to special laboratories. Lasers can cause serious health concerns to the skin, organs and tissue damage as a result of extended exposure or staring into the beam. Thermal radiation resulting from heat generated during extended laser contact is also a concern. Corneal or retinal burns or both are possible, depending upon the laser

wavelength. Corneal or lenticular opacities (cataracts), or retinal injury may be possible from lengthy exposure to excessive levels of ultraviolet radiation due to photochemical effects. Skin burns are possible from acute exposure to high levels of laser radiation. At some specific ultraviolet wavelengths, skin carcinogenesis may occur. Some materials used in lasers (i.e. excimer, dye and chemical lasers) can release toxic substances such as hazardous particulates and gaseous products. Additionally, lethal

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“ There are other secondary hazards associated with lasers that the user should be aware of. ”

## Diagnostic Reference Levels

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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 (un)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 be taken. Satisfying a DRL for a particular exam or protocol does not imply that the protocol or procedure is fully optimized. If



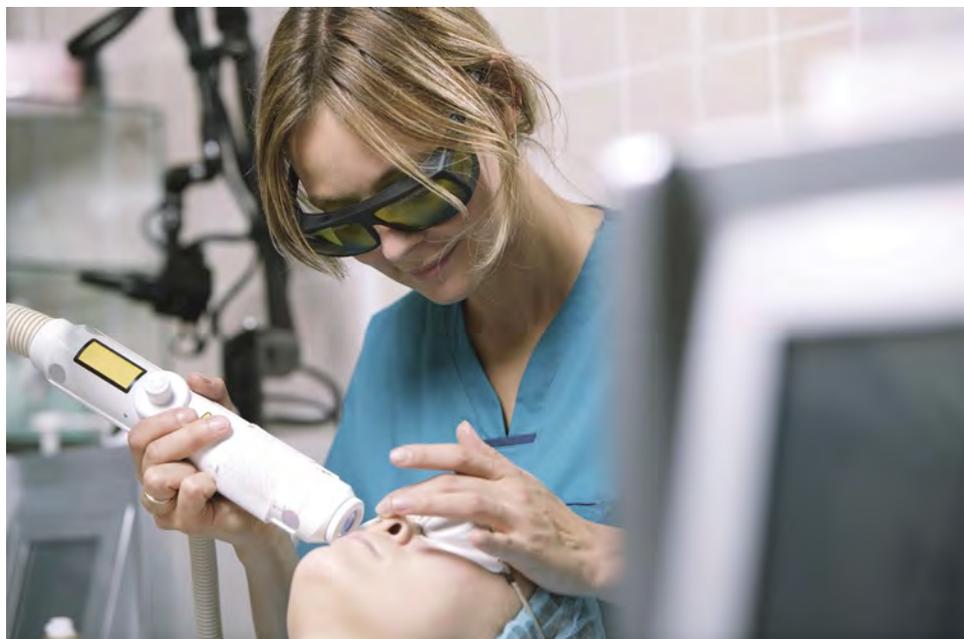
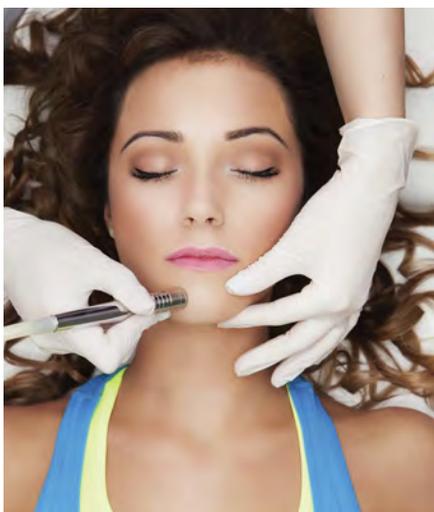
an exam or protocol is identified that consistently exceeds the DRL, justification must be provided. Facility staff should consult with a qualified medical physicist regarding the measurement of patient doses to compare these doses to the DRL. The qualified medical physicist must make measurements so that the facility can determine the patient entrance dose from the technique factors they routinely use for each patient exam. Patient entrance

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# Laser Safety

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electrical hazards may be present in most lasers, particularly in high power laser systems. There are other secondary hazards associated with lasers that the user should be aware of. These include: cryogenic coolant hazards, excessive noise from high energy lasers, x-radiation from faulty high-voltage (>15 kV) power supplies, explosions from faulty capacitors and flash lamps, and fire hazards. In the United States several organizations concern themselves with laser safety. These organizations include the American National Standards Institute (ANSI); the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA); the Department of Labor's Occupational Safety and Health Administration (OSHA); and the Council of Radiation Control Program Directors (CRCPD). Several state governments and the CRCPD have developed a model state standard for laser safety.



## Lasers and North Carolina Regulations:

North Carolina Administrative Code Title 15A Radiation Protection Section, Chapter 11- Radiation Protection Section, incorporates federal laser rules, CDRH/FDA 21CFR Part 1040, within :15 NCAC 11 .0117(a) (3). Performance Standards for Light-Emitting Products. 21CFR1040.10 is specifically for the manufacture of laser products. Currently, the Radiation Protection Section has a Memorandum of Agreement (MOA) which allows the Agency to report laser and radiofrequency issues to the North

Carolina Occupational Safety and Health Division (NCOSH), North Carolina Department of Labor.

NCOSH laser standards incorporate the federal OSHA standards and are referenced in 13 NCAC 07F .0203 Subpart D -- Occupational Health and Environmental Controls. (See federal regulation, 29 CFR 1926.54, Nonionizing Radiation)

At the present time, OSHA does not have a comprehensive laser safety standard. Instead, the OSHA policy has been to rely on ANSI Z136.1, the generally accepted industry laser standard, and FDA laser manufacturer requirements. ●

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## Diagnostic Reference Levels

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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. ●

## Infection Control

### What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control?



To meet the MQSA requirements for infection control, the facility must:

Provide written documentation that describes the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of those materials. The procedures used by the facility must comply with applicable federal, state and local regulations as well as the manufacturer's recommendations.

Have documentation (e.g., logs or charts) indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials. In those cases where there has not been an episode of contamination since

the last inspection, the facility should make that clear to the inspector.

#### **What does the FDA mean by referenced material?**

Referenced material is documentation from the manufacturer of the disinfectant or the mammography equipment with instructions to adequately disinfect the equipment. This documentation may be necessary to support your policies for infection control.

#### **What is MSDS?**

The Material Safety Data Sheet (MSDS) is a document that contains information on the chemical make-up, use, storage, handling, emergency procedures and potential health effects related to a hazardous material. The MSDS must be available for chemicals used for disinfection of the mammography equipment. ●

Beginning on January 1, 2014 facilities providing mammography services in N.C. are now required to identify each patient's individual breast density classification based on the Breast Imaging Reporting and Data System established by the American College of Radiology. If the facility determines that a patient has "heterogeneously" or "extremely" dense breasts, the results letter/notification provided to the patient must include the following statements:

"Your mammogram indicates that you may have dense breast tissue. Dense breast tissue is relatively common and is found in more than forty percent of women. The presence of dense tissue may make it more difficult to detect abnormalities in the breast and may be associated with an increased risk of breast cancer. We are providing this information to raise your awareness of this important factor and to encourage you to talk with your physician about this and other breast cancer risk factors. Together,



you can decide which screening options are right for you. A report of your results was sent to your physician."

The law can be found on the Radiation Protection Website.

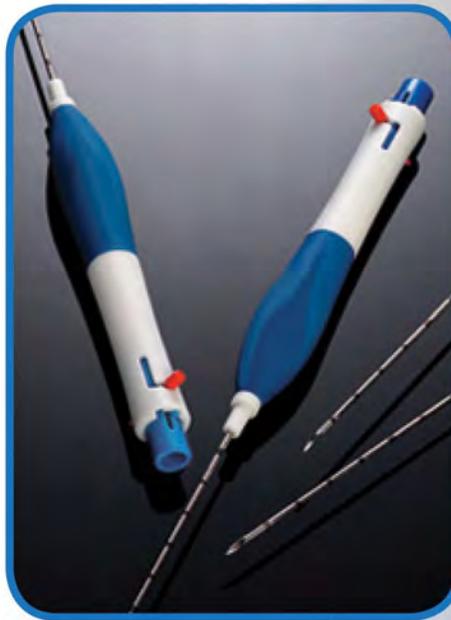
Information about breast density and mammography can be found on the NC Radiological Society Website. ●

# Mammography Screening Certificate



The mammography screening certificate displayed in many mammography suites in N.C. is issued by

the N.C. Department of Health and Human Services, Acute Home Care / CLIA Section. Questions regarding renewal of expired screening certificates should be directed to their main phone number 919-855-4620. This certificate is not required to be displayed and is not needed for the annual facility inspection. ●



## Post-Procedure Marker Placement



As part of a breast biopsy procedure a metal marker may be placed at the biopsy site.

After the biopsy and marker placement, the patient usually has a unilateral mammogram. If a/the biopsy is done utilizing a stereotactic unit, the post-biopsy mammogram is usually taken on the stereotactic unit. The patient can be moved to the facility's mammogram room to have the exam performed on the regular mammography system.

FDA Guidance: Mammography equipment used solely for interventional procedures and not FDA/MQSA certified is currently excluded from MQSA regulations. The mammographic images obtained

on these units are not under MQSA unless the facility bills these images as separate mammograms.

The Centers for Medicare & Medicaid Services (CMS) has published the CMS Guide for Mammography Billing Codes to assist facilities with the recent changes to coding for mammograms.

The ACR has provided guidance for unique mammography billing issues here: [ACR Coding Q&A](#).

What are your policies for post procedure mammograms? Facilities that conduct interventional breast procedures should address their billing procedures in their policy manual. This should help identify any billing issues and provide useful information for your annual inspection. ●



## What is LOINC?



“ ...interoperable health information technology infrastructure to improve the quality and efficiency of health care ”



Recently we have received questions about LOINC as it relates to MQSA. LOINC is an acronym for

“Logistical Observation Identifiers, Names and Codes” and is distributed by the Regenstrief Institute, Inc., an informatics and healthcare research organization. The loinc.org website identifies it as “A universal code system for identifying laboratory and clinical observations” that serves to “enable exchange and aggregation of electronic health data from many independent systems. “

The federal governments’ National Institute of Health website states: “The U.S. Department of Health and Human Services (HHS) has set a goal for the nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care. Achieving this goal will require that key clinical data elements are captured or recorded in detailed,

standardized form (using standard vocabularies, codes and formats) as close to their original sources (patients, health care providers, laboratories, diagnostic devices, etc.) as possible. If these standardized clinical data can also be used to generate HIPAA-compliant billing transactions automatically, this will provide another incentive for adoption of clinical data standards. For automated generation of bills from clinical data to become a reality, robust mappings from standard clinical terminologies to the HIPAA code sets must be created.”

The confusion regarding association

with MQSA most likely results from the LOINC link to the federal government terms of the U.S. Department of Health and Human Services and HIPAA. LOINC, however, has no relationship with the Mammography Quality Standards Act and the inspection process. ●



## Contact Information Radiation Protection Section

### Registered Facilities

- Notification of Registration Forms  
XrayNORS@dhhs.nc.gov
- Changes to Registration  
XrayNORS@dhhs.nc.gov
- X-ray Inspection Responses  
drp.x-ray@dhhs.nc.gov
- Mammography Inspection Responses  
drp.mammo@dhhs.nc.gov
- Out of State Mobile Location Form  
XrayService@dhhs.nc.gov
- Report an Overexposure  
XrayService@dhhs.nc.gov

### Service Providers

- Report of Assembly/FDA 2579  
FDA2579@dhhs.nc.gov
- Report of Sales and Installations Form  
FDA2579@dhhs.nc.gov
- Service Provider Registration Form  
XrayService@dhhs.nc.gov
- Service Provider Registration Changes  
XrayService@dhhs.nc.gov
- Service Provider Notice of Violation Responses  
XrayService@dhhs.nc.gov
- Shielding Plan Review Form  
shieldingdesign@dhhs.nc.gov

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# MQSA National Statistics

Certified facilities (as of October 1, 2014)	8,720
Certification statistics (as of January 1, 2015)	
Total certified facilities/ Total accredited units	8,734 / 13,871
Certified facilities with FFDM2 units/ Accredited FFDM units	8,303 / 13,306
FY 2014 inspection statistics (as of January 1, 2015)	
Facilities inspected	1,808
Total units at inspected facilities	2,853
Percent of inspections where the highest noncompliance was a:	
Level 1 violation	0.7%
Level 2 violation	11.1%
Level 3 violation	1.8%
Percent of inspections with no violation	86.3%
Total annual mammography procedures reported, as of January 1, 2015 <sup>1</sup>	38,816,406

<sup>1</sup> This number is an aggregate of the total number of procedures performed annually as reported by facilities to their accreditation bodies. Facilities are asked to disclose this information at their initial accreditation, and then at the time of their re-accreditation, which takes place once every three years. FDA began collecting these data in 1998. The aggregate does not reflect the current number of procedures performed at these facilities, but only the numbers reported by them during the three-year period prior to the current date. We have aggregated only the numbers reported by certified, non-Veterans Administration facilities.

<sup>2</sup> FFDM - Full Field Digital Mammography unit.

Taken from the FDA website ●

## Contact Information Radiation Protection Section

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**North Carolina Department  
of Health and Human Services**

**Division of Health  
Service Regulation**

**Radiation Protection Section**

**Main Number:  
919-814-2250**

**Mailing address:  
1645 Mail Service Center  
Raleigh NC 27699-1645**

**Physical address:  
5505 Creedmoor Road  
Suite 100  
Raleigh, NC 27612**

*\* RPS has dedicated service  
e-mail addresses for submitting  
forms and inspection responses. ●*



State of North Carolina  
Department of Health & Human Services  
Division of Health Service Regulation  
Radiation Protection Section  
www.ncdhhs.gov • <http://www.ncradiation.net>  
NC DHHS is an equal opportunity employer and provider.  
01/2015