

Radiation Compliance Guide

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Table of Contents

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|--|-----------|
| 1. Requirements if You Own, Possess or Use X-Ray Equipment in NC | Pages 1-2 |
| 2. Steps to Install X-Ray Equipment or Register a Facility | Pages 3-4 |
| 3. Application For Registration of Radiation Units and Facilities Healing Arts | Page 5 |
| 4. Medical X-Ray Inspection Checklist | Pages 6-7 |
| 5. Purpose and Guidelines for a Safety Program | Pages 8-9 |
| 6. X-Ray Fee Amounts | Page 10 |
| 7. Notice to Employees | Page 11 |
| 8. Letter from Healthtech, Inc | Page 12 |

Radiology Compliance Branch

RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

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

- Have all equipment registered with this agency.
- Report when equipment has been rendered not in use, sold or transferred immediately.
- Notify the Radiation Protection Section if you sell your practice, or you will continue to be billed for those units.
- Review your Notice of Registration for accuracy. If any information on the form has changed, the section's staff should be notified immediately. This includes equipment, address, contacts and contact information.
- Provide access to authorized representatives who have the authority to enter any facility at all reasonable times for the purpose of determining compliance. Reasonable hours are the operating hours of the business Monday through Friday.

If you buy a practice, all documents regarding equipment should be obtained from the previous owner during the purchase agreement. Another option is that you may select a service provider and have the necessary work performed prior to beginning to operate your equipment. Any items not in compliance will have to be brought into compliance. Once a facility is registered, inspections may occur at any time thereafter. You do not need to contact the section to schedule an inspection.

An inspection may take one to four hours with a smaller practice and one or more days for larger facilities. Inspection frequency varies from every two to four years depending on the type of practice. Inspections are unannounced and based on performance.

Performance-based means the radiation safety policies written specific to your facility will be reviewed. Inspectors will observe radiation safety practices in your facility and may interview employees about radiation safety practice in the facility. Records related to equipment and registration are reviewed, which takes up the majority of the time.

Equipment measurements in the rooms can be made with little interference in patient flow. Typically, a radiographic room may take 15 to 20 minutes, fluoroscopic rooms may take 20 to 30 minutes, dental intra-oral rooms may take five minutes and cephalometric rooms may take 20 to 30 minutes. The section's inspectors generally

coordinate with the initial contact at the facility to work through the rooms without impeding the work flow and locate an area where they can do record review when equipment rooms are not available.

Upon completion of the inspection, an exit interview is offered with the desire that the most responsible persons can participate. Inspectors will conduct an informal summary of the inspection results. Some situations require rule review and research after inspection. Final inspection results are mailed to the facility from the section's central office following the conclusion of an inspection. Response times to violations are 15 calendar days for a Level 1 and 30 business days for levels II, III and IV from receipt of the letter. If unable to participate in the exit interview, a business card is left so that the inspector can be contacted at the office to answer any questions or concerns regarding the inspection process.

An inspection checklist and other materials are available at <http://www.ncradiation.net>. The Web site is a wonderful tool to assist you in preparation for an inspection or registering equipment. If you click on X-Ray, a state map with contact information will provide the regional inspector name and phone number in your area. If you need help with the registration process, please call the Raleigh office at (919) 814-2250 and ask for the registration coordinator.



Radiology Compliance Branch
RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

Steps To Install X-Ray Equipment or Register a Facility

Inspections: The agency conducts unannounced periodic radiation safety inspections based on the type of practice and geographic locations. An Inspection checklist is available at agency website: [Link to Inspection Checklist](#). Registrants are responsible for maintaining all documentation described in steps below for review during inspections. Inspectors are assigned to regions throughout the state. Phone numbers and names for each region are available at [X-ray region map](#) if you have questions.

STEP 1 **Shielding Plan:** The registrant should contact service provider who is registered with Radiation Protection Section (RPS) to perform and submit a shielding plan review to this agency **prior to construction and or structural modifications and prior to installation of equipment**. Contact a registered service provider with Class III or Class IV under the service provider’s listing and the appropriate category - medical, dental, veterinary, etc. depending on the type of practice and X-ray equipment. [Link to Service Provider Listing: Class III, IV, and V](#). The service provider will submit the shielding plan to the N.C. Radiation Protection Section for review.

*Note: Steps 1 and 2, Shielding plan and acknowledgement are not required for industrial applications, bone density units and *standard mammography units. **(Shielding plans are still required for stereotactic, 3D and tomosynthesis mammography units)**

STEP 2 **Acknowledgement Letter:** Once a shielding plan review is submitted to the agency by the service provider, the shielding plan will be reviewed and evaluated and a letter of acknowledgment will be mailed to the registrant. Instructions regarding any actions needed by the registrant after installation of the X-ray equipment will be included on page 2 of the acknowledgment letter. (* see note in step 1)

STEP 3 **Equipment Installation:** After the registrant receives an acknowledgement letter from the agency, contact a service provider that is registered with the agency for installation of equipment. Contact a service provider that has a “Class II” under their listing and the appropriate category – medical, dental, etc. depending on the type of practice and X-ray equipment. The registrant should provide a copy of the acknowledgement letter and shielding plan review to the installer. **The equipment must be installed exactly as projected on the acknowledged shielding plan.**

STEP 4 **Post-Installation Survey:** (required on all installations): The registrant must schedule to have a post-installation radiation survey with a service provider who is registered with this agency. The survey must be performed within 30 days following initial operation of the unit(s). Contact a service provider that has a “Class V” under their listing and the appropriate category – medical, dental, veterinary, etc.

STEP 5 **Registration:** New registrants must complete and submit the application for registration to the agency: [Link to Applications](#). Existing facilities can use a copy of their Notification of Registration for minor changes and when the location or contact information has not changed.

STEP 6 **Report of Installation:** The service provider performing the installation of the X-ray equipment must complete a federal Form FDA 2579 "Report of Assembly" for each unit installed. A copy of this report must be provided to the registrant, the FDA, and the Radiation Protection within 15 days of completion of the installation.

Note: Equipment exempt from the federal Form FDA 2579 such as Industrial, analytical and some veterinary, the service provider is still required to report the installation to this agency on the agency form. [Link to Report of State Installation for Non-federal Assembly of X-ray Systems Agency Form](#)

STEP 7 **Radiation Safety Program:** Registrant must designate a Radiation Safety Officer for their facility and develop a Radiation Safety Program. A guidance document, assessment tool and tutorial on how to develop a safety program are online at [Guides for Written Safety Program](#). Registrants need assistance should contact a service provider registered to perform those services. Contact a service provider with a "Class IX – General Health Physics Consulting – Design of Safety Program" under their listing. [Link to Complete List of Service Companies & Services](#)

STEP 8 **Signs, Regulations and Subscription for updates:** Required postings such as the radiation warning sign, Notice to Employees and the latest version of regulations can be printed on the agency web site. [Link to Required Postings](#)
[Link to N.C. Regulations for Protection Against Radiation](#)

STEP 9 **Personnel Dosimetry:** All registrants must provide personnel dosimetry for each X-ray operator. The service provider providing personnel dosimetry services must be registered with this agency. The registrant should look for a service provider with a "Class VIII" under their listing. [Link to Service Listing Class VIII Personnel Dosimetry](#)

STEP 10 **Registration Updates:** Registrants are required to submit updates when any change renders the information contained in the application for registration or notice of registration no longer accurate. A change of ownership, facility or billing contact must be reported on the application for registration. Relocation of a registrant, equipment, new installations, X-ray component (control panel only) changes or a change in the status of equipment use such as active or not in use, sold or donated must be reported. Registration updates require signature of an authorized person and date.

STEP 11 **Safety Culture:** Registrants are required to be knowledgeable of rules and regulations regarding radiation safety. Registrants should subscribe to our list serve to receive updates and newsletters regarding changes that could affect facilities. [Link to X-ray News Subscription](#)

The agency website is current with answers to all your questions and valuable resources. <http://www.ncradiation.net/Xray/xray.htm>. The registrant and the radiation safety officer should actively seek to promote and cultivate a safety culture in their facility. [Link to Safety Culture](#)



RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

APPLICATION FOR REGISTRATION OF RADIATION UNITS AND FACILITIES HEALING ARTS

- Initial Registration New Satellite Office Amended Registration We've moved
 Change of Ownership Name change

Reg. No. _____

1. FACILITY INFORMATION (Required): Location of the facility & x-ray units, each physical address requires a separate registration listing all of the units at the location.

Name of Facility: _____ Phone: (____) _____

Physical Address: _____ Fax: (____) _____

City: _____ County: _____ State: _____ Zip Code + 4 _____

- Type of Facility: Chiropractic Dental Education Government Health Dept Imaging Center Hospital
 Clinic Physician Podiatry Veterinary Therapy Mobile Service

2. FACILITY CONTACT (Required if different from most responsible person at #4 below): Person (such as the director of imaging or office administrator) at the facility who might be delegated responsibilities such as making major decision regarding corrective action and general operations and purchasing equipments.

Name of Facility Contact: _____ Title or Position: _____

Mailing Address: _____ Phone: (____) _____

City: _____ State: _____ Zip Code + 4 _____ Fax: (____) _____

Email: _____

3. BILLING or ACCOUNTING SPECIALIST (Required): Person with authority to pay annual invoice.

Name of Contact: _____ Title or Position: _____

Billing Address: _____ Phone: (____) _____

City: _____ State: _____ Zip Code + 4 _____ Fax: (____) _____

Email: _____

4. MOST RESPONSIBLE PERSON / CORPORATION (Required): Person who is the financial owner such as CEO or corporate officer.

Corporate Name: _____ Email: _____

Name of Most Responsible Person: _____ Title or Position: _____
Address: _____

Phone: (____) _____

City: _____ State: _____ Zip Code + 4 _____ Fax: (____) _____

Type of Ownership: Individual(s) Limited Partnership General Partnership Corporation LLC PA PC

5. INSTALLER INFORMATION or PREVIOUSLY INSTALLED FOR:

Old Registration _____

Business Name: _____

Address: _____ Phone: (____) _____

City: _____ State: _____ Zip Code: _____



Radiology Compliance Branch
RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

MEDICAL X-RAY INSPECTION CHECKLIST
(Medical-Dental-Podiatry-Chiropractic-Veterinary)

North Carolina Regulations for Protection Against Radiation rule references shown in brackets below:

General Documents:

- Waivers on file (if applicable) [.0108(a)]
- Report of Sale / Installation Report (*FDA 2579 Form*) [.0115]
- Current Notice of Registration [.0209]; [.1002(a)(2)]
- Copy of Shielding Design (Plan Review) [.0603(a)(2)(A)]; [.0603(b)]
- Copy of Letter of Acknowledgement [.0603(a)(2)(A)]
- Copy of Radiation Area Survey (Post Install) [.0603(a)(2)(B)]; [.0603(c)]

Operating Procedures - Written Safety Procedures - Radiation Protection Program:

- Operating Procedures [.0603(a)(1)(B)]; [.1002(a)(3)]
- Written Safety Procedures [.0603(a)(1)(D)]; [.0603(a)(1)(H)(i) & (ii)]
- Current copy radiation protection program [.1603(a)]
- Annual radiation protection program review by registrant [.1603(c)]; [.1636]

Records:

- Training documentation of person responsible for radiation protection [.0203(b)(3)]
- Records of maintenance or modification, which affect the useful beam [.0603(a)(2)(C)]
- Records of notification if occupational doses exceed 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue [.1004(b)(1)] (*effective 1/1/14*)
- Personnel monitoring and exposure records [.1614]; [.1640]

Posting of Signs or Other Information:

- Fluoroscopic Outputs (if applicable) [.0605(3)(d)]
- Current** copy of N.C. Regulations for Protection Against Radiation (*Eff. October 1, 2013*) [.1002(a)(1)]

Copies of the regulations may be in electronic form or printed.

Applicable sections of the regulations for Medical X-ray are the following:

10A NCAC 15 [.0100]; [.0200]; [.0600]; [.1000]; [.1100] and [.1600]:

- To view or print applicable sections:
Consolidated PDF of Regulations
- Print entire regulations:
N.C. Regulation Online

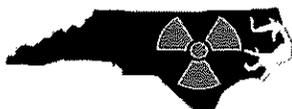
- Notice to Employees [.1002(c)]
- Radiation Caution Signs [.1623]; [.1624]

Other Items of Interest: (if applicable)

- Brand, type and emitting color of film & screens (*Film/Screen combination speed*)
- Film storage location
- Digital Exposure Ranges per exam (manufacture recommendations)
- Patient Images storage policy and procedures
- Average number of exposures per week



Radiology Compliance Branch RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

Purpose and Guidelines for a Safety Program

The Key to Radiation Safety – A Written Radiation Protection Program

A radiation protection program is intended to ensure that all activities and operations involving the use of X-rays are performed in such a way as to protect users, staff, patients and the public from exposure to unnecessary radiation in practices that use X-ray equipment.

The basis of this plan is to maintain all radiation exposures As Low As Reasonably Achievable, which is abbreviated and known as ALARA. This philosophy – ALARA – is defined as making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, remaining consistent with the purpose for which the licensed or registered activity is undertaken.

The written radiation protection program is a unique document for each facility, based upon the scope of activities provided by each practice, and is required by the *North Carolina Regulations for Protection Against Radiation*. Rule .1603, titled "Radiation Protection Programs," states that each licensee or registrant shall develop, document and implement a radiation protection program. Since each facility is unique, each written radiation protection program should be customized to its specific activities. Certain records and documents as listed in the regulations that may be consistent for all regulated facilities; however, the day-to-day activities performed within a facility will differ and should be documented to provide radiation protection safety for staff and the public.

Developing a customized radiation safety program can be challenging, so the following information is being provided to assist you when developing or updating your facility's written safety program.

In the past, a model guide for the Preparation of Operation and Safety Procedures has been used but is no longer available from the Radiation Protection Section. This guide has been replaced with a written safety program outline. If a facility has an old model guide and would like to continue with that format, a few items must be updated to ensure it is specific to the facility. To update your written safety program:

- ❖ Compare the model guide to the safety program outline. Be sure to add activities staff is performing that were not addressed in the model guide.
- ❖ Change the model guide heading to the facility's name.
- ❖ Remove sections that do not apply to the facility.
- ❖ Remove the following words in the document – 'model procedures' and 'sample set of procedures.'



An outline of a written safety program is available on the Radiation Protection Web site at www.ncradiation.net, or it can be obtained by calling (919) 814-2250. Ensure the facility's name is in the written safety program. Carefully, review each item listed in the outline to see if it applies to an activity that must be performed or is being performed at the facility. To determine if an item is required or is already being done at the facility and should be included on the written radiation safety program, ask the questions *who, what, when, where, why or how* in order to list the item(s) on the outline and include the appropriate safety measures. It is important to remember to detail exactly how a facility performs an activity on your written radiation safety program.

- ❖ Available online at <http://www.ncradiation.net> are reference guides and links that may be helpful when developing a written safety program. A few of the guides and links are ALARA, Pregnancy-Employee/Patient, Signs and Posting, and links to CRCPD and ARRT.

Once a written safety program is developed, it must be effectively implemented. Every individual working in or near sources of radiation should be trained on the scope, content, and requirements of the program. The regulations require an annual review of the program, which provides a perfect opportunity for the facility to evaluate the written program against actual practice and either update the program or retrain the staff in the proper procedures. Documentation must be available for review during inspections.



15A NCAC 11 .1105 X-RAY FEE AMOUNTS

(a) Annual fees for persons registered pursuant to provisions of Section .0200 of this Chapter are as listed in the following table:

| Type of Registered Facility | Letters Appearing in Registration Number | Facility Plus First X-ray Tube | Each Additional X-ray Tube |
|-----------------------------|--|--------------------------------|----------------------------|
| Chiropractors | C | \$ 180.00 | \$ 24.00 |
| Dentists | D | \$ 180.00 | \$ 24.00 |
| Educational | E | \$ 130.00 | \$ 22.00 |
| Government | G | \$ 130.00 | \$ 22.00 |
| Podiatrists | H | \$ 180.00 | \$ 24.00 |
| Industrial | I | \$ 180.00 | \$ 24.00 |
| Industrial Medical | IM | \$ 260.00 | \$ 33.00 |
| Health Departments | L | \$ 260.00 | \$ 33.00 |
| Hospitals | M | \$ 390.00 | \$ 44.00 |
| Physicians | P | \$ 180.00 | \$ 24.00 |
| Industrial Radiography | R | \$ 380.00 | \$ 44.00 |
| Services | S | \$ 260.00 | \$ 0.00 |
| Therapy | T | \$ 400.00 | \$ 50.00 |
| Veterinarians | V | \$ 130.00 | \$ 22.00 |
| Other | Z | \$ 180.00 | \$ 24.00 |

(b) Annual fees for out-of-state persons granted permission to use sources of radiation in this state pursuant to provisions of Rule .0211 of this Chapter are the same as that provided for in the applicable category specified in Paragraph (a) of this Rule.

*History Note: Authority G.S. 104E-9(a)(8); 104E-19(a);
Eff. July 1, 1982;
Amended Eff. July 1, 2011; August 1, 2007; August 1, 2002; July 1, 1989.*



NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION | RADIATION PROTECTION SECTION



NOTICE TO EMPLOYEES

Standards for Protection Against Radiation (Section .1600); Notices: Instructions and Reports to Workers (Section .1000); Employee Protection

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to:

1. Apply the North Carolina Regulations for Protection Against Radiation (10A NCAC 15) to work involving radioactive materials and/or sources of radiation;
2. Post or otherwise make available to you a copy of the Radiation Protection Commission regulations, certificates, licenses or registrations, and the operating procedures which apply to the work you perform, and explain their provisions to you; and
3. Post Notices of Violation involving radiological working conditions and orders.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Radiation Protection Commission regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in 10A NCAC 15 .1604, .1609 and .1610. These rules specify limits on exposure to radiation and to concentrations of radioactive material in air.
2. If you work where personnel monitoring is required, and if you request information on your radiation exposures,
 - (a) Your employer must give you a written report of your radiation exposures upon termination of your employment, and
 - (b) Your employer must advise you annually of your exposure to radiation.

POSTING REQUIREMENT

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, pursuant to 10A NCAC 15 .0200 and .0300, by the N.C. Department of Health and Human Services, to permit employees working in or frequenting any portion of a restricted area to read and observe on the way to or from any particular work location to which the document applies.

WHAT IS COVERED BY THESE REGULATIONS

1. Limits on exposure to radiation and radioactive materials in restricted and unrestricted areas;
2. Measures to be taken after accident exposure;
3. Personnel monitoring, surveys, and equipment;
4. Caution signs, labels and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding agency inspections; and
7. Related matters.

YOUR RESPONSIBILITY AS A WORKER

For your own protection and the protection of your co-workers, you should familiarize yourself with the provisions of the Radiation Protection Commission regulations and the operating procedures which apply to the work you perform.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of N.C. Department of Health and Human Services. In addition, any worker or representative of workers who believes that there is a violation of the N.C. Radiation Protection Act, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to: *Section Chief, Radiation Protection Section, 1645 Mail Service Center, Raleigh, NC 27699-1645*. The request must set forth the specific grounds for the notice and signed by the employee or the representative of the employee. The agency will make all reasonable efforts to protect your identity where appropriate and possible. During inspections, agency inspectors may confer privately with workers; any worker may bring to the attention of the inspectors any past or present condition which he or she believes contributed to or caused any violation as described above.

OTHER EMPLOYEE PROTECTIONS

Federal Law prohibits an employer from firing or otherwise discriminating against you for bringing safety concerns to the attention of your employer or the N.C. Radiation Protection Section. Your employer cannot fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the N.C. Radiation Protection Section or raise a safety issue or otherwise engage in protected activities. If you feel that you have been discriminated against for identifying violations or safety concerns, you may file a complaint with the Employment Discrimination Bureau of the North Carolina Department of Labor (800) 625-2267 or <http://www.nclabor.com>). They will advise you of the proper procedures to file a complaint.

HOW TO CONTACT THE RADIATION PROTECTION SECTION

The Radiation Protection Section is located at 5505 Creedmoor Road, Suite 100, Raleigh NC 27612. Agency representatives may be reached by telephone at (919) 814-2250 during normal weekday work hours (8 a.m. – 5 p.m.). After normal business hours, calls may be directed to the N.C. Emergency Management Operations Center at (800) 858-0368. You may also obtain additional information about the agency online <http://www.ncradiation.net>.

The Radiative Material Branch 24 hour emergency line is (919) 602-7151.

North Carolina Department of Health and Human Services • Division of Health Service Regulation • Radiation Protection Section
N.C. DHHS is an equal opportunity employer and provider. 9/2015



7215-104 Ogden Business Lane
Wilmington, NC 28411
877.570.8324
910.686.6086

To: NCCA Members
From: Mike Newsome

Dear Doctor,

Radiation compliance in North Carolina can be sometimes very difficult to follow, unless each of us takes the time to familiarize ourselves with all the rules and regulations. Radiation compliance is beneficial both for patients and healthcare workers, and we all have to make a more conscience effort in reducing the radiation exposure.

As a small business owner, I totally understand the hardship of finding the time to go through hours of research. In an effort to save you time and money, I have put together a set of documents that can guide you through the compliance steps and answer most of your questions regarding the requirements. Most of the documents come straight from the web site of the North Carolina Department of Health and Human Services (www.ncradiation.net).

As you continue to move into the digital age of radiography, it is my hope that the information I provided will help to make your workplace safer. Thank you again for your continued support.

Sincerely,
Mike Newsome
President

Email: mnewsome@healthtechnc.com
Web site: www.healthtechnc.com



Web site: www.chiropracticsupplyhouse.com