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: <u>Link to Inspection Checklist</u>. 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 <u>X-ray region map</u> 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 <u>are</u> still required for stereotactic, 3D and tomosynthesis mammography units)

- STEP 2Acknowledgement 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 postinstallation 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.

1645 Mail Service Center - Raleigh, North Carolina 27699-1645 Phone: (919) 814-2250 *Visit our website <u>www.ncradiation.net</u>* Steps To Install X-ray & Register a Facility Rev.4/03/13

State of North Carolina | Division of Health Service Regulation | Radiation Protection Section | Radiology Compliance Branch

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 7Radiation 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 8Signs, Regulations and Subscription for updates:
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 9Personnel 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
- STEP 10Registration 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 11Safety 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. <u>http://www.ncradiation.net/Xray/xray.htm</u>. The registrant and the radiation safety officer should actively seek to promote and cultivate a safety culture in their facility. <u>Link to Safety Culture</u>

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