

Radiology Compliance Branch
RADIATION PROTECTION SECTION



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

PLAN REVIEW REQUIREMENTS FOR SERVICE PROVIDERS

[Download shielding plan review form](#)

Rule .0603(a)(2)(b)

Plan Review, Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing X-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.

Rule .0604(b)(1)(C)

Structural Shielding

- (1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .01604 and .1611 of this Chapter.

- (C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.

Rule .0605(9)(b)

A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

Rule .0607(j)

Structural Shielding

- (1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.
- (2) When intraoral X-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.

Rule .0210(a) and (c)

- (a) No person registered pursuant to Rule .0205 of this Section for X-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such machines and equipment when placed in operation shall meet the applicable requirements of these Rules.

- (c) No person registered pursuant to Rule .0205 of this Section shall install radiation machines which are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued written acknowledgement of receipt of any facility and shielding design required in Rule .0603 of this Chapter

- ❖ **Plan Reviews** – The existing or proposed location of each component must be indicated. The shielding requirements for all primary and secondary barriers must be indicated in the shielding recommendations. Each plan review must include recommendations of the qualified expert, i.e. location of exposure switch, operator position, lead aprons, position of doors (closed, locked, interlocked), etc. Existing or proposed construction material must be identified including walls, doors and windows. Indicating that the “existing shielding is adequate” will not meet this requirement.



- ❖ **Shielding Design Form** – A “*Shielding Design Form*” must be submitted as the cover sheet of the plan review to expedite processing
- ❖ **Drawings** – Plan review drawings must be to scale with the scale indicated on the drawing. All primary and secondary barriers must be properly labeled to correspond with the shielding recommendations. The facility name, physical address, and date must be indicated on all drawings (shielding and survey). The adjacent areas (hallway, offices, bathrooms, etc.) must be identified on the drawing.
- ❖ **View Window Size** – Pursuant to .0604(b)(1)(C), the window or mirror system shall be large enough and so placed that the operator can see the patient without having to leave the protected area during exposures. However, if a specific view window size is projected in the plan review, the view window must meet the size requirement or a revised plan must be submitted.
- ❖ **Installations** – Pursuant to **.0210(a) and (c)**, it is the installing service provider’s responsibility to verify that RPS has acknowledged the plan review. Prior to installation, the installing service provider should obtain a copy of the plan review and acknowledgement letter from the facility or the service provider that performed the plan review. The equipment must be installed according to the plan review and must meet all requirements of the Regulations. If there are discrepancies with the plan review and/or the planned installation orientation, the installation shall not be performed until a new plan review is submitted & acknowledged.
- ❖ **Open Access Areas** – Open access area at the end of the wall in dental offices must have a barrier to prevent access to adjacent areas.
- ❖ **Digital Equipment** – Analog equipment being replaced by digital equipment will require a new plan review.
- ❖ **Out of State Mobiles** – A plan review and survey is required and must be performed by a N.C. Registered Service Provider (please refer to our website for a list of service providers).
- ❖ **Mobiles Used as Stationary Units** – A plan review and survey is required.
- ❖ **C-Arms** – Pursuant to **Rule .0605(9)(b)**, the need for lead aprons and portable shielding for scatter radiation must be included in the recommendations.
- ❖ **Retention of Plan Reviews by RPS** – RPS is in the process of converting to an electronic filing system; therefore, plan reviews and surveys may be purged from a facility’s file. It is ultimately the facility’s responsibility to maintain records of the plan review, acknowledgement letter, and survey.
- ❖ **Requests for Plan Reviews and Acknowledgment Letters:** The facility should be contacted for copies of these documents. If a facility is unable to provide these documents, the service provider that performed the plan review should be contacted. If the documents still cannot be located, a “*Plan Review Search Request Form*” may be submitted to the RPS **as a last resort**. If RPS does not have the requested documents, a plan review must be performed and submitted for acknowledgement. Please contact RPS for the request form.
- ❖ **Change of Ownership** – A new plan review and area radiation survey must be performed when equipment is replaced.

The ultimate goal of RPS is to cultivate and maintain a cooperative working relationship with our regulated community. The agency strives to be efficient and effective with its resources in order to fulfill its responsibilities to the citizens of North Carolina.

Construction Section:

Some X-ray equipment may be intended for installation in a licensed health care facility. The Construction Section performs plan review and inspections of the following facility types: hospitals, hospital based outpatient clinics, ambulatory surgery centers, nursing homes, adult and family care homes, hospice, state owned mental health facilities, mental health hospitals, intermediate care facilities for individuals with intellectual disabilities (ICF/IID), and mental health 24-hour residential facilities, women health service centers, child care centers and jails. Inquiries concerning the Construction Section should be addressed to the Construction Section of the Division of Health Service Regulation at 1800 Umstead Drive, Raleigh NC 27603, (919)855-3893

For such machines that are subject to Construction Section approval, the Radiation Safety Section will withhold issuing a registration permit for the radiation machine until both of the following have occurred:

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

Inquiries concerning the Construction Section should be submitted to:

DHSR/ Construction Section

Physical Address: 1800 Umstead Drive, Raleigh, NC 27603

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

Phone: 919-855-3893

Certificate of Need Section:

Some radiation machines and radiological services are also subject to Certificate of Need (CON) approval. The following radiation equipment requires a Certificate of Need (CON) from the CON Section, DHSR:

- cardiac catheterization equipment
- Gamma Knives
- linear accelerators and simulators
- lithotripters
- Positron Emission Tomography (PET) Scanners

In addition, any radiographic equipment where the aggregate cost or value of the equipment exceeds \$750,000. *See definition of "major medical equipment," NCGS 131E .176(14o)*. Examples include but are not limited to: computed tomography (CT) scanners and vascular imaging systems.

Also, diagnostic centers with nuclear medicine, X-ray, mammography, fluoroscopy, and/or bone density equipment, where the total cost or fair market value of all of the medical diagnostic equipment used by the facility and the costs associated with the equipment exceed \$500,000. *See definition of "diagnostic center," NCGS 131E .176(7a)*.

For more information see: [CON Section, DHSR](#) or [CON Law](#)

For machines that are subject to CON approval, the Radiation Safety Section will withhold issuing a registration permit for the radiation machine until both of the following have occurred:

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

Inquiries concerning the Certificate of Need Section should be submitted to:

DHSR Certificate of Need Section

Physical Address: 809 Ruggles Drive, Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center, Raleigh, NC 27699-2704

Phone: 919-855-3873